Note: Only UKRF may negotiate changes to this agreement.

UNIVERSITY OF KENTUCKY RESEARCH FOUNDATION

CLINICAL STUDY AGREEMENT

for

PROTOCOL NUMBER _____

This agreement is entered into as of _____, 20___, by and between_____ located at _____ ("SPONSOR") and the University of Kentucky Research Foundation, as agent and on behalf of the University, its employees, and agents, located at 109 Kinkead Hall, Lexington, Kentucky, 40502 ("UNIVERSITY").

WITNESSETH

The clinical study contemplated by this Agreement is of mutual interest to the UNIVERSITY and SPONSOR, and will further the instructional and research objectives of the UNIVERSITY in a manner consistent with its status as a non-profit, tax exempt educational institution.

1. SCOPE OF WORK

   The UNIVERSITY agrees to use its best efforts to conduct the clinical study described in Protocol No._____entitled "_____" and attached as Exhibit A ("Study").

   In this undertaking, the UNIVERSITY agrees to use reasonable efforts to perform the clinical Study in conformance with the protocol and all applicable laws, rules and regulations relating to the conduct of this study, particularly such laws, rules and regulations concerning the protection of human subjects and those promulgated by the Food and Drug Administration.

2. PRINCIPAL INVESTIGATOR

   This Agreement will be under the direction of _____, Principal Investigator ("PRINCIPAL INVESTIGATOR"). In the event_____shall be unable to complete this clinical Study as principal investigator and a successor acceptable to both UNIVERSITY and SPONSOR, is not available, this Agreement shall be terminated in accordance with Article 15.

3. PERFORMANCE PERIOD

   The clinical Study shall commence on _____ and will terminate on [insert either "completion of the Study" or a specified date] unless otherwise provided in this Agreement. Expenditure directly related to this project may be incurred by the Principal Investigator after the end date stated here.

4. REPORTING

   UNIVERSITY agrees to notify SPONSOR at the earliest time possible of any deviations from the Protocol necessary to protect the safety, rights or welfare of patients enrolled in the clinical Study and any serious adverse reactions of patients in the study.

UNIVERSITY shall prepare and submit to sponsor all case report forms and such other reports as required by the protocol.

SPONSOR shall have reasonable access to all laboratory and clinical data generated pursuant to the protocol at a time mutually agreed upon by the parties to the extent permitted by applicable law and regulatory authority.

5. PAYMENT TERMS

SPONSOR will pay UNIVERSITY a one-time non-refundable study initiation fee of $ _____ upon execution of this Agreement. Initiation costs are separate from the per patient costs and include preparation of the research study for presentation to the Institutional Review board (IRB) and maintenance thereafter, preparation of the budget and any negotiations with SPONSOR. The initiation fee is non-refundable.

In addition to the study initiation fee, a one-time non-refundable $3,000.00 fee for IRB review will be assessed and invoiced separately.

SPONSOR shall pay UNIVERSITY $_____ per completed patient, up to a maximum of

$_____ , based on enrollment of _____ patients in accordance with the protocol. A detailed payment schedule is outlined in Exhibit B.

Partial payment will be made for patients who do not complete the protocol. The payments will be pro-rated based on the number of visits and/or work completed.

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.

Payments shall be made payable to the University of Kentucky Research Foundation and forwarded to:

_____
_____
_____
TAX I.D. NO. 61-6033693

6. CONFIDENTIALITY

Subject to the provisions of Article 7, the UNIVERSITY and PRINCIPAL INVESTIGATOR agree to use all reasonable diligence to prevent disclosure to third parties any confidential information disclosed to it under this Agreement and marked by SPONSOR as confidential for a period of three (3) years from the date of disclosure. Confidential information shall be disclosed to the UNIVERSITY in writing and marked “confidential”, or if disclosed orally or in other documentary form shall be reduced to writing and marked “confidential” within thirty (30) days thereafter. UNIVERSITY may disclose information to staff members, employees or medical students necessary for the conduct of the study. This non-disclosure obligation shall not apply to:

a. Information that is now in the public domain or subsequently enters the public domain through no fault of the PRINCIPAL INVESTIGATOR or UNIVERSITY;

b. Information that is presently known or becomes known to PRINCIPAL INVESTIGATOR or UNIVERSITY from its own independent sources;

c. Information that PRINCIPAL INVESTIGATOR or UNIVERSITY receives from any third party not under any confidential obligation to keep such information confidential;

d. Information independently developed by PRINCIPAL INVESTIGATOR or UNIVERSITY without use of SPONSOR'S confidential information;

e. Information that is required to be disclosed by law.

7. PUBLICATIONS

The UNIVERSITY shall have the right, consistent with academic standards, to publish the results of the Clinical Study provided such publication does not constitute a violation of Article 6.

Prior to submission for publication or presentation, the UNIVERSITY will provide the SPONSOR thirty (30) days for review of the manuscript or other material for such publication. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreeable to the SPONSOR and UNIVERSITY or PRINCIPAL INVESTIGATOR.

In addition, if requested in writing and with reasonable justification, the UNIVERSITY will withhold such publication an additional sixty (60) days to allow for filing a patent application. Provided that UNIVERSITY and PRINCIPAL INVESTIGATOR comply with provisions in Articles 7 of this Agreement, nothing in this Agreement shall prohibit UNIVERSITY and PRINCIPAL INVESTIGATOR from the publication of all information generated at the UNIVERSITY during the Study necessary for the accurate interpretation and presentation of said medical research and scientific data.

Notwithstanding the foregoing, UNIVERSITY 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 twelve (12) months following completion of this Agreement, UNIVERSITY will be free to publish.

8. INTELLECTUAL PROPERTY

It is recognized and understood that the existing inventions and technologies of SPONSOR and UNIVERSITY are their separate property, respectively ("Existing Inventions and Technology"), and are not affected by this Agreement and neither party shall have any claims to or rights in such Existing Inventions and Technologies of the other party. Other than Inventions (as defined below), title to any other inventions or discoveries conceived and/or reduced to practice in the performance of this Study solely by UNIVERSITY employees ("University Inventions") shall be owned by the UNIVERSITY and shall be promptly and fully disclosed in writing to SPONSOR.

Information directly generated in fulfilling the Protocol and/or included in SPONSOR's CFRs shall be the property of SPONSOR ("Data"). Title to any Data and inventions or discoveries conceived and/or reduced to practice under this Agreement and using the Study Drug, the Protocol, or any of SPONSOR's Confidential Information, whether by UNIVERSITY, SPONSOR, or any Study Personnel, individually or jointly ("Inventions") shall be owned by

SPONSOR. UNIVERSITY shall promptly and fully disclose all Inventions in writing to SPONSOR. UNIVERSITY, on behalf of itself and Study Personnel, hereby assigns (i) all of its intellectual property and proprietary right, title and interest in and to the Data and Inventions to SPONSOR; and (ii) all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. UNIVERSITY shall cooperate and assist SPONSOR to execute and shall cause Study Personnel to execute all documents reasonably necessary for SPONSOR to secure, perfect, effectuate and preserve SPONSOR's ownership rights in and to the Data and Inventions.

UNIVERSITY may use Data as necessary for the accurate interpretation and presentation of medical research and scientific data in its publications as permitted in Article 7.

Information and disclosures made hereunder are Confidential Information, and the non-owning party shall protect the information in accordance with the obligations of Article 6.

The UNIVERSITY, consistent with the UNIVERSITY'S patent policy, will offer SPONSOR the first opportunity to enter into negotiations for a royalty-bearing license for UNIVERSITY'S rights in such University Invention. SPONSOR shall have sixty (60) days from the date of its receipt of UNIVERSITY's disclosure of the University Invention to exercise this option. Such license shall be exclusive and worldwide to the maximum extent permitted by the established policy of UNIVERSITY with a reasonable royalty and will provide SPONSOR with an exclusive right to make, have made, use and sell such University Invention and the right to sublicense such rights.

9. RECORD ACCESS AND RETENTION

SPONSOR and its agents shall have access to all information resulting from each Study to the extent allowed by applicable law and informed consent documentation. The UNIVERSITY shall permit SPONSOR and its agents, during normal business hours and at mutually agreeable times, to inspect and make abstracts of records and reports collected and generated by the UNIVERSITY and/or the Investigator in the course of conducting the Study and to inspect the facilities at which the Study is conducted for the purposes of verifying compliance with this Agreement, the applicable Protocol and the accuracy of information provided by the UNIVERSITY or the Investigator to SPONSOR in connection with the Study. The UNIVERSITY shall make the Investigator and other appropriate Personnel reasonably available to SPONSOR and its agents to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of SPONSOR or its agents, the UNIVERSITY shall, and shall cause the Investigator to, correct any errors or omissions in such records and reports. Notwithstanding the foregoing, the UNIVERSITY shall have no obligation to alter Study subject medical records in any manner inconsistent with generally accepted medical record practices. The UNIVERSITY shall maintain Study records consistent with the requirements of applicable laws and regulations.

10. PUBLICITY

Neither UNIVERSITY nor SPONSOR shall use the name of the other party or any of its employees in connection with any press release, advertising, promotional literature, or any other publicity matters without the express prior written consent of the other.

11. GOVERNING LAW

This Agreement shall be governed by the laws of the Commonwealth of Kentucky.

12. NOTICES

All notices required to be given under this Agreement and all correspondence with regard to any such notice hereunder shall be in writing and delivered in person, sent by certified mail or fax transmission to the individuals named and at the addresses listed below:

UNIVERSITY

| Scientific Representative | Administrative Representative |
|---|---|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

SPONSOR

| Scientific Representative | Administrative Representative |
|---|---|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

13. INDEMNIFICATION

a. SPONSOR shall defend, indemnify and hold harmless the PRINCIPAL INVESTIGATOR, UNIVERSITY OF KENTUCKY RESEARCH FOUNDATION and the UNIVERSITY OF KENTUCKY and their trustees, IRB, officers, agents, subcontractors, and employees from any and all liabilities, claims, actions or suits arising out of or in connection with the administration or use of the Study drug(s) or device(s) or procedures required by the Protocol. Notwithstanding the foregoing, SPONSOR shall not be responsible for claims, actions or suits, or any portion thereof, arising from:

   i. the gross negligence of UNIVERSITY;

   ii. actions by the UNIVERSITY in violation of applicable laws or regulations; or

   iii. a material breach of the protocol governing the Study.

Deviations from the terms of the Protocol that may arise out of necessity do not constitute negligence or willful malfeasance provided that UNIVERSITY shall promptly notify

SPONSOR of any such deviations.

b. UNIVERSITY agrees to use its best efforts to notify SPONSOR within ten (10) working days of UNIVERSITY receipt of any complaint or claim relating to any loss subject to this indemnification;

c. UNIVERSITY agrees that the SPONSOR has control over the defense and settlement of any such complaint or claim(s). SPONSOR shall have the right to select defense counsel and to direct the defense or settlement of any such claim or suit so long as the UNIVERSITY and any named individual defendants agree to the proposed defense counsel, defense plan and/or settlement, which agreement may not be unreasonably withheld. In the event UNIVERSITY and/or any named individual defendant refuses to accept defense plan and/or settlement, SPONSOR'S required indemnification of that party shall be terminated and the UNIVERSITY and/or named individual defendant may continue its own defense, settlement, etc. at its/their sole cost and expense. SPONSOR shall be liable for costs of defense incurred prior to the decisions of UNIVERSITY and/or any named individual defendants to be responsible for its/their own defense.

d. The SPONSOR shall provide diligent defense against or settlement of any claims brought or actions filed with respect to the subject of the indemnity contained herein, whether such claims or actions are rightfully or wrongfully brought or filed. The SPONSOR shall have the right to settle claims at the SPONSOR'S sole expense.

e. The UNIVERSITY and/or any named individual defendant shall reasonably cooperate with the SPONSOR and its legal representatives in the investigation and defense of any claim or suit covered under the Agreement. In the event a claim or action is or may be asserted, the UNIVERSITY shall have the right to select and to obtain representation by separate legal counsel. If a party exercises such right, all costs and expenses incurred by that party for such separate counsel shall be borne by the party.

f. SPONSOR shall maintain a policy or program of insurance or self-insurance to support the indemnification obligations set forth herein at levels acceptable to UNIVERSITY. SPONSOR will provide evidence of its insurance in a form acceptable to UNIVERSITY upon execution of this Agreement.

14. SUBJECT INJURY

The SPONSOR shall cover the cost of reasonable and necessary medical expenses incurred by a study subject as a result of procedures performed in accordance with the Study, including, but not limited to, any cost resulting from an adverse reaction from administering the Study Drug, provided such expenses are in no way attributable to the gross negligence or misconduct of the UNIVERSITY.

15. SPONSOR NOTIFICATIONS

If SPONSOR has a regulatory obligation to monitor the conduct of the Study, during and after the Study, SPONSOR shall provide the UNIVERSITY with reports of routine data and safety monitoring activities and promptly, but not longer than thirty (30) days from discovery, notify UNIVERSITY of any information discovered through the monitoring process upon discovery that could affect the safety of Study participants, affect willingness of Study participants to continue participation in the Study, influence conduct of the Study, or alter the IRB’s Study approval.

SPONSOR shall also notify UNIVERSITY if the results of the Study directly affect safety or medical care of Study participants and UNIVERSITY will communicate such information to Study participants. SPONSOR agrees to report the information required by this section for a period of two (2) years from the end of the Study.

16. TERMINATION

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

a. SPONSOR receives notification from Federal or State Regulatory Authorities to terminate said study;

b. SPONSOR or the UNIVERSITY determines that the UNIVERSITY, after a reasonable opportunity, is unable for any reason to perform the study satisfactorily as required in the protocol;

c. PRINCIPAL INVESTIGATOR is unable or unwilling to continue the study and a successor acceptable to both UNIVERSITY and SPONSOR is not available.

d. Breach by either party of the material terms of this agreement.

Written notice of its decision to exercise such termination right shall be given to the UNIVERSITY by the SPONSOR or to the SPONSOR by the UNIVERSITY by Certified Mail, delivered fifteen (15) days before said termination of the study. Immediately upon receipt of notice of termination by either the SPONSOR or the UNIVERSITY, the UNIVERSITY 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 UNIVERSITY shall be as stated in Article 5.

Termination or completion of this Agreement, however, shall not relieve the obligations undertaken by the parties in articles 5, 6, 7, 8, 10, 11, 13, 14 and 15.

17. GENERIC DRUG ENFORCEMENT ACT OF 1992

UNIVERSITY represents that the UNIVERSITY is not debarred. The UNIVERSITY will not knowingly use in any capacity the services of any person debarred under subsection 306(A) or 306(B) of the Generic Drug Enforcement Act of 1992 in connection with any of the services performed by UNIVERSITY for this study hereunder.

UNIVERSITY will promptly disclose in writing to SPONSOR if any person who is performing services to this study hereunder is debarred or if any debarment action, suit, claim, investigation, legal or administrative proceeding is pending or, to the best of UNIVERSITY'S knowledge, threatened, relating to the debarment of UNIVERSITY or any person performing services for this study hereunder.

18. EXPORT CONTROLS

It is understood that UNIVERSITY is subject to United States Laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities, and that its obligations hereunder are contingent on compliance with applicable U.S. export laws

and regulations (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979). The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by the SPONSOR that the SPONSOR will not re-export data or commodities to certain foreign countries without prior approval of the cognizant government agency. While UNIVERSITY agrees to cooperate in securing any license which the cognizant agency deems necessary in connection with this Agreement, SPONSOR cannot guarantee that such licenses will be granted.

It is the normal operational policy of the SPONSOR that its work and the results of its research undertakings are exempt from compliance with US governmental export regulations under the Fundamental Research Exemption. Should the SPONSOR provide or transmit under this agreement any technology or data that is subject to governmental export regulatory compliance and does not qualify as exempt under the Fundamental Research Exemption, UNIVERSITY reserves the right to refuse acceptance of such material or data and/or to terminate this agreement. Such refusal or termination shall not be considered a breach of contract obligations.

19. DATA SECURITY

SPONSOR acknowledges that UNIVERSITY is legally bound by the Kentucky Personal Information Security and Breach Investigation Procedures and Practices Act, KRS 61.931, 61.932 and 61.933 (the "Act"). The parties do not intend that SPONSOR will be provided with any Personal Information (“PI”) as that term is defined by KRS 61.931(6). In the unlikely event that SPONSOR, its agents, or representatives view PI or inadvertently receives any data containing PI, it will make no record of any such PI and immediately return any paper or electronic copies.

20. DISPUTE RESOLUTION

SPONSOR and UNIVERSITY agree to enter into negotiations to resolve any dispute arising under this Agreement. Both parties agree to negotiate in good faith to reach a mutually agreeable settlement within a reasonable amount of time. If negotiations are unsuccessful, either party may seek a resolution in a court of competent jurisdiction.

21. AMENDMENTS

This Agreement and the Protocol may only be extended, renewed or otherwise amended by the mutual written consent of parties hereto.

22. ENTIRE AGREEMENT

This Agreement represents the entire understanding of the parties with respect to the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern.

23. SEVERABLITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

24. INTEGRATION

The protocol and Exhibits A and B are incorporated in this Agreement by reference.

25. ASSIGNMENT

Neither this Agreement nor the rights or obligations hereunder shall be assignable or otherwise transferred or subcontracted by UNIVERSITY or SPONSOR without the other's prior written consent. Any attempted assignment will be void.

26. INDEPENDENT CONTRACTOR

In undertaking to perform this study for SPONSOR, it is understood that UNIVERSITY is doing so as an independent contractor and not as an employee of SPONSOR.

In WITNESS WHEREOF the Parties have caused this Agreement to be executed by their duly authorized representatives.

SPONSOR

By_____

Authorized Official

Title_____

Date_____

UNIVERSITY OF KENTUCKY RESEARCH FOUNDATION

By_____

Kim C. Carter

Title_____

Date_____

While not a legal party to this Agreement, I, the Principal Investigator, have read and understand this Agreement and accept the terms as they relate to my activities as the Principal Investigator.

PRINCIPAL INVESTIGATOR

By_____

Date_____