INDUSTRY SPONSORED CLINICAL TRIAL AGREEMENT

THIS INDUSTRY SPONSORED CLINICAL TRIAL AGREEMENT made and effective as of the date of last signing (herein the “Effective Date”) by and between ____________________(herein “Sponsor”), a for-profit corporation, and the UNIVERSITY OF CINCINNATI, a state institution of higher education organized under Chapter 3361 of the Ohio Revised Code, on behalf of its ____________________, having an office at University Hall, Suite 530, 51 Goodman Drive, Cincinnati, Ohio 45221-0222 (herein “UC”).

WHEREAS, the research program contemplated by this Agreement is of mutual interest and benefit to UC and to the Sponsor, and will further the instructional and research objectives of UC in a manner consistent with its status as a nonprofit, tax-exempt, educational institution, NOW, THEREFORE, the parties hereto agree as follows:

1. STATEMENT OF WORK. UC agrees to use its reasonable efforts to perform the research program (herein the “Research Program”) as set forth in Exhibit A. UC shall not make changes to the Research Program without the prior written consent of Sponsor. UC shall ensure that staff members who are participating in the Research Program have been properly informed about the requirements of the Research Program and the rules and regulations under which the Research Program is to be conducted, and have the necessary qualifications, experience, authorizations and supervision to perform their assigned duties.

2. PRINCIPAL INVESTIGATOR. ____________________ will supervise the research. If, for any reason, that person is unable to continue to serve as Principal Investigator, Sponsor and UC shall attempt to find a successor acceptable to both parties. If such a successor is not available, this Agreement shall be terminated as provided in Article 6.

3. PERIOD OF PERFORMANCE. The research shall be conducted during the period beginning on __________ and ending on __________(herein the “Termination Date”) and will be subject to renewal only by mutual, written agreement of the parties.

4. RESEARCH DEVICE OR PRODUCTS. Sponsor shall provide the study device or products and other components as appropriate for completion of the Research Program (“Research Materials”) to UC, free of cost. All Research Materials shall remain the property of Sponsor during the Research Program and receipt, use, and disposition of the Research Materials shall be accounted for by UC. Research Materials shall be used in connection with the Research Program and shall not be analyzed, transferred to a third party or used for any other purpose. Upon the completion of the Research Program or termination of this Agreement, unless otherwise required by law or so notified by Sponsor in writing, all remaining Research Materials will be stored under appropriate conditions by UC and then returned to Sponsor at Sponsor’s expense.

5. REIMBURSEMENT OF COSTS. In consideration of the foregoing, the Sponsor agrees to support the research set forth in Exhibit A, including all direct and indirect costs consistent with UC’s policy for the conduct of this research effort, by paying the amounts as specified in the Budget, Exhibit B provided that the total of such costs does not exceed $________ U.S. dollars. UC and Principal Investigator agree that the funds provided by Sponsor under this Agreement will be used solely in connection with the Research Program. Neither UC nor Principal Investigator shall seek or accept reimbursement from any third party payor for a procedure or treatment paid for or supplied by
Sponsor under this Agreement. UC agrees that this compensation is sufficient to complete the Research Program. UC is responsible for compensating Principal Investigator and any person or entity UC employs or contracts with directly for services hereunder. The subject stipend amount, if any, will be specified in the informed consent form and the Budget. No payment will be due or payable by Sponsor for costs not included in the Budget, any costs resulting from the failure to follow the Research Program, or costs related to a subject who cannot be evaluated or whose medical data cannot be used due to the failure of UC or the Principal Investigator to comply with applicable laws, regulations, and guidelines.

6. PAYMENT. Payments shall be made to UC by the Sponsor in U.S. dollars, 50% due and payable upon receipt of invoice 30 days after execution of the agreement by both parties and the remainder due upon receipt of invoice after deliverables are met. Payments to UC will be sent to the address indicated on the invoice, or as otherwise specified in Exhibit C.

Invoices should be sent to:
Name: __________________________
Company: ________________________
Address: _________________________
Phone: __________________________
E-mail: _________________________

7. EARLY TERMINATION.
A. Should UC breach this Agreement or become unable to perform hereunder, Sponsor shall have the right to terminate this Agreement. Sponsor shall notify UC of its intention to do so, and termination shall become effective sixty (60) days thereafter if UC is unable to cure the breach or rectify the problem.

B. Failure of Sponsor to pay any amount required hereunder within thirty (30) days after receipt of an invoice from UC shall be cause for UC to terminate this Agreement. UC shall notify Sponsor of its intention to do so, and termination shall become effective sixty (60) days thereafter if Sponsor has not made such payment in full.

C. Termination under this Article 6 does not relieve Sponsor of the obligation to reimburse all costs and non-cancelable expenses and commitments incurred in the performance of the Research Program prior to termination, provided that such reimbursement shall not exceed the total project cost as specified in Exhibit B, and further provided that UC shall use reasonable efforts to refrain from incurring additional costs and expenses to the extent possible. Any unearned funds not due to UC but already paid to UC shall be returned to Sponsor within forty-five (45) days of the effective date of termination.

D. Either party may terminate this Agreement upon thirty (30) days’ written notice to the other party.

8. REPORTS AND CONFIDENTIAL INFORMATION
A. From time to time during the term of this Agreement, UC will provide Sponsor with written summaries of research progress. UC will provide a summary report at completion.
B. As used herein, “Confidential Information” shall mean information, know-how, samples, drawings or data, technical or non-technical, relating to the Research Program, that originates with either party, is disclosed or provided to the other and is clearly labeled as “Confidential”. If disclosed orally, the Confidential Information shall be promptly reduced to written form and labeled as “Confidential”. Sponsor and UC each acknowledge that the Confidential Information shall remain the sole and exclusive property of the disclosing party. Neither party shall use any Confidential Information in any manner in competition against, or contrary to the interests of, the other party. The recipient may use the originator’s Confidential Information for purposes of this Agreement, but agrees neither to use for any other purpose nor to disclose or provide such Confidential Information to any third party at any time during the term of this Agreement for a period of ten (10) years after the expiration or termination of this Agreement, except as follows:

1. To the extent that such Confidential Information was known to the recipient from sources other than the originator prior to its disclosure hereunder, and this is demonstrably documented in written records made by recipient prior to such disclosure; or

2. To the extent that such Confidential Information in fact is public knowledge prior to or after its disclosure, other than through acts or omissions attributable to the recipient; or

3. To the extent that such Confidential Information was disclosed or provided to the recipient by a third party who did not derive such information from the originator; or

4. The parties acknowledge that UC is a state entity subject to Section 149.43 of the Ohio Revised Code. To the extent disclosure is required by law or judicial process, UC shall notify Sponsor in advance of releasing any Confidential Information. Reasonable efforts shall be made to provide this notice in sufficient time to allow the Sponsor to seek an appropriate protective order or modification of any disclosure.

C. Each recipient specifically agrees not to export or re-export any information and/or technical data and/or products in violation of any applicable USA laws and/or regulations.

D. Each recipient will retain control of Confidential samples received hereunder and will not provide them to parties who are not bound by this Agreement.

E. In compliance with the Association for Accreditation of Human Research Protection Programs (“AAHRPP”), nothing herein shall be deemed to prevent the disclosure of study data and results to participants and their healthcare providers by sponsor or investigator when such disclosure is reasonably necessary to ensure the safety and appropriate medical care for such participants.

9. PUBLICATIONS. UC reserves the right to publish the results of its research performed hereunder. Before publishing, however, UC agrees to submit copies of any manuscript proposed for publication to Sponsor at least thirty (30) days in advance of the presentation or publication date, and if Sponsor does not ask to defer publication within thirty (30) days after receipt of the manuscript so that patent applications may be filed, UC may proceed with publication. In the event Sponsor asks to defer
publication, UC shall not publish or otherwise disclose to any third party any of the information contained in the manuscript until such time as a patent application has been filed or the expiration of sixty (60) days after the date of submission of the manuscript to Sponsor, whichever occurs first.

10. INTELLECTUAL PROPERTY.

A. Subject to Section 3345.14 of the Ohio Revised Code, title to any discovery or invention conceived or first reduced to practice in the performance of the research program, herein “Project Invention,” shall be assigned to UC if all of the inventors are UC employees; shall be assigned jointly to Sponsor and UC if the inventors include employees of both parties; and shall be assigned to Sponsor if all the inventors are employees of Sponsor.

B. If Sponsor asks UC to file patent applications on a Project Invention, Sponsor agrees to pay the costs of filing, prosecution and maintenance of the resulting patent application(s) and patents maturing therefrom. Sponsor shall notify UC of those foreign countries in which it desires a license, in sufficient time for UC to satisfy the patent law requirements of that country.

C. If UC asks Sponsor to pay for the filing, prosecution or maintenance of a patent application or patent on a UC Project Invention, and Sponsor refuses, Sponsor’s option rights with respect to such patent application or patent shall terminate immediately.

D. In consideration for research support and patent expenses received hereunder, UC grants to Sponsor an option (herein “the Option”) to acquire a license to any UC Project Invention, including any patent applications and patents resulting therefrom, according to the terms and conditions set forth herein.

(1) The Option will expire on the Termination Date of this Agreement.

(2) Sponsor may exercise the Option by written notice to UC at any time prior to its expiration declaring Sponsor’s intent to negotiate a license agreement with UC (herein the “License Agreement”). The parties shall begin to negotiate in good faith toward execution of the License Agreement under commercially reasonable terms within sixty (60) days after receipt by UC of written notification by Sponsor.

(3) Sponsor agrees promptly to notify UC in writing at any time during the Option Period if Sponsor determines not to exercise the Option, and further agrees to provide UC in reasonable detail in writing the basis for such determination. The Option shall expire immediately on such notification.

E. Title to any copyrights or copyrightable material first produced in the performance of the Research Program shall remain with UC. UC shall grant to the Sponsor an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use and reproduce all such copyrightable materials, including computer software and its documentation specified to be developed and delivered under the Statement of Work, for Sponsor’s internal (non-commercial) purposes. UC further grants to Sponsor an option to negotiate a non-exclusive (or exclusive subject to third party rights, if any) royalty-bearing license to use, reproduce, display, distribute, and perform such computer software and its documentation for commercial purposes, such option to expire on the Termination Date. Computer software for which a
patent application is filed shall be subject to paragraphs A-D above.

F. Tangible Research Property ("TRP") is defined for purposes of this Agreement as tangible (or corporeal) items produced in the course of research projects supported by UC or by external sponsors. TRP includes such items as: biological materials, engineering drawings, computer software, integrated circuit chips, computer databases, prototype devices, circuit diagrams, equipment. In the event that Subcontractor elects to establish property rights other than patents to any TRP developed during the course of the research, Subcontractor and UC will determine the disposition of rights to such property by separate agreement. UC will, at a minimum, reserve the right to use and distribute TRP for non-commercial research purposes.

G. All licenses granted pursuant to this Article 9 become effective as of the date the parties sign a subsequent license agreement.

11. USE OF NAMES. Neither party will use the name of the other in any publication, advertising, or other form of publicity without the written permission of the other.

12. ANIMAL AND HUMAN STUDIES. Any use of human subjects or live, vertebrate animals in the performance of research hereunder shall comply with all applicable laws, government regulations, and guidelines, including, without limitation Good Clinical Practice, regulations governing study investigators and the protection of human subjects, adverse event reporting, and all applicable privacy and security laws, including, without limitation, the United States Health Insurance Portability and Accountability Act of 1996, and regulations promulgated thereunder ("HIPAA").

13. INDEMNIFICATION. Sponsor agrees to indemnify, defend and hold harmless the University of Cincinnati, its Board of Trustees and Institutional Review Board, and any of its trustees, directors, affiliates, officers, employees, physicians or agents, including Principal Investigator and sub-investigators, from and against any and all damages, liabilities, costs and expenses (including reasonable attorneys’ fees) that they may suffer as a result of claims, demands, costs or judgements against them arising out of activities carried out pursuant to this Agreement, including, but not limited to personal injury, illness or death to participants in the study arising from or caused by the Research Materials being investigated pursuant to the Research Program or the negligent or intentional acts or omissions of Sponsor or Sponsor’s officers, employees, contractors or agents in connection with the Research Program and/or the performance of this Agreement.

14. MEDICAL TREATMENT. In compliance with AAHRPP Element I.8.A., Sponsor will reimburse site for the reasonable cost of medical treatment required by participants in the study due to injury or illness caused by that subject’s participation in the study to the extent that such injury or illness is not covered by the participant’s medical or third-party health insurance, and is not caused by the negligence of the employees or agents of the site.

15. PROTECTED HEALTH INFORMATION. UC agrees to use reasonable efforts to ensure that it will be able to provide any and all Research Program data to Sponsor, its representatives, collaborators and licensees. Such acts shall include without limitation, obtaining in a manner consistent with HIPAA, authorization from each human subject to provide the subject’s PHI (as defined by HIPAA) to Sponsor, its representatives, collaborators and licensees for the purpose of conducting the Research Program and inspecting records relevant to the Research Program.
16. **SERIOUS ADVERSE EVENT REPORTING.** UC shall report any serious adverse events ("SAE") associated with the Research Materials provided under this Agreement within 24 hours after identification of the SAE. UC shall report any unanticipated adverse device effects ("UADE") within ten (10) working days after the identification of the UADE. Sponsor may terminate this Agreement immediately in the event UC fails to comply with its reporting obligations.

17. **INSTITUTIONAL REVIEW BOARD.** UC shall obtain the approval of its Institutional Review Board ("IRB") prior to commencing the Research Program and shall ensure that the IRB oversees the conduct of the study. UC shall comply with the directives of the IRB with respect to the Research Program, and shall notify Sponsor to the extent any such directives vary from the Research Program. In the event UC is unable to obtain IRB approval of the Research Program, the parties may terminate this Agreement without further obligation.

18. **CONFLICT OF INTEREST.** UC and Primary Investigator represent that they have advised Sponsor in writing prior to execution of this Agreement of any known relationship between UC or Primary Investigator and a third party, including, without limitation, competitors of Sponsor, that would: (a) in any way present a conflict of interest with the services to be performed under this Agreement; (b) present a significant opportunity for the disclosure of Sponsor’s Confidential Information; or (c) in any way prevent either party from carrying out the terms of this Agreement. Except with respect to known relationships identified above, UC represents that the terms of this Agreement are valid and binding obligations of UC, and are not inconsistent with any other contractual and/or legal obligations it may have, or with UC’s policies or the policies of any institution or company with which it is associated.

19. **DEBARMENT.** Each party represents that neither it, nor any of its employees or agents performing hereunder, have ever been, are currently, or are the subject of a proceeding that could lead to it or such employees or agents becoming debarred or disqualified under applicable laws and regulations relating to clinical trials. Each party further represents that if, during the term of this Agreement, it, or any of its employees or agents performing hereunder, become or are the subject of a proceeding that could lead to that party, employee or agent becoming debarred or disqualified under applicable laws and regulations relating to clinical trials, each party shall promptly, and in no event later than two (2) days after its first knowledge of such proceeding or debarment, notify the other party, and the other party shall have the right to immediately terminate this Agreement.

20. **NO REFERRALS.** The parties acknowledge and agree that: (a) the compensation set forth is provided solely for the purposes of the study and represents the fair market value of the services provided by UC, negotiated in an arms-length transaction and has not been determined in a manner which takes into account the volume or value of any referrals or business otherwise generated between UC and Sponsor; and (b) no provision of this Agreement is intended as an inducement or offer to give or receive anything of value, either directly or indirectly, for the referral of patients or for the arranging or furnishing of any item or service for which payment may be made by a government health care program. In the event that UC or the Principal Investigator recommends Sponsor’s products to any person or entity during the term of this Agreement, UC or the Principal Investigator, as applicable, shall disclose this relationship with Sponsor in an effective manner.

21. **RELATIONSHIP OF THE PARTIES.** UC’s relationship to Sponsor under this Agreement is that of an independent contractor, and neither party has authority to bind or act on behalf of the other party. UC represents that Principal Investigator’s relationship to UC is that of an employee, and UC further agrees to be responsible for compensating Principal Investigator for his/her services. Further,
the parties acknowledge that they are not “business associates” as that term is defined under HIPAA, and neither party shall undertake any activity in this Agreement that could be construed as establishing such a “business associate” relationship. UC acknowledges that it is not an agent of Sponsor, and has no authority to speak for, represent or obligate Sponsor in any way without first receiving written authority to do so from Sponsor.

22. **NOTICES.** Any notices required to be given or which shall be given under this Agreement shall be in writing delivered by first class mail (air mail if not domestic) or overnight courier service (e.g., FedEx) addressed to the parties as follows:

**UNIVERSITY OF CINCINNATI**

David S. Gearring, Director
Sponsored Research Services
University Hall, Suite 530
51 Goodman Drive
University of Cincinnati
P.O. Box 210222
Cincinnati, Ohio 45221-0222

Phone: (513) 556-4358  
Fax: (513) 556-4346  
E-mail: gearridd@uc.edu

**SPONSOR**

In the event notices, statements, and payments required under this Agreement are sent by certified or registered mail or overnight courier service by one party to the other party at its above address, they shall be deemed to have been given or made as of the date so mailed, otherwise as of the date received. Any party may change its notice address and contact person by giving notice of same in the manner provided.

23. **ASSIGNMENT.** This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and the successors to substantially the entire business and assets of the respective parties hereto. This Agreement shall not be assignable by either party without the prior written consent of the other party; provided, however, that Sponsor may, without such consent, assign this Agreement and its rights and obligations hereunder to an affiliate or in connection with the transfer or sale of all or substantially all of its business pertaining to this Agreement, or in the event of any merger or consolidation or change in control or similar transaction.

24. **GOVERNING LAW.** The validity and interpretation of this Agreement and the legal relation of the parties to it shall be governed by the laws of the State of Ohio and the United States.

25. **EXPORT CONTROLS.** It is understood that UC 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 UC agrees to cooperate in securing any
license which the cognizant agency deems necessary in connection with this Agreement, UC cannot guarantee that such licenses will be granted.

26. **FORCE MAJEURE.** A party shall not be responsible to the other party for failure to perform any of the obligations imposed by this agreement, provided such failure shall be occasioned by fire, flood, explosion, lightning, windstorm, earthquake, subsidence of soil, failure or destruction, in whole or in part, of machinery or equipment or failure of supply of materials, discontinuity in the supply of power, governmental interference, civil commotion, riot, war, strikes, labor disturbance, transportation difficulties, labor shortage, or any cause beyond the reasonable control of the affected party (“Force Majeure”), provided that the affected party shall give prompt notice thereof to the other party and complete its obligations as promptly as reasonably practicable following cessation of the cause or circumstance of such Force Majeure.

27. **WARRANTY DISCLAIMER.** Nothing in this Agreement shall be construed as:

A. A warranty or representation by UC as to the validity or scope of any patent.

B. A warranty or representation that anything made, used, sold or otherwise disposed of under any license that may be granted upon exercise of the Option is or will be free from infringement of patents, copyrights and trademarks of third parties;

C. An obligation to bring or prosecute actions or suits against third parties for infringement;

D. Conferring rights to use in advertising, publicity or otherwise any trademark or the name of UC or Sponsor; or

E. Granting by implication, estoppel or otherwise any licenses under patents of UC or Sponsor other than patent(s) identified herein, regardless whether such other patents are dominant or subordinate to any such patent(s).

Except as expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT ANY ACTIVITY PERFORMED OR DELIVERABLE PROVIDED HEREUNDER SHALL BE FREE OF INFRINGEMENT OF THIRD-PARTY INTELLECTUAL PROPERTY RIGHTS OR OTHER RIGHTS.

28. **ENTIRE AGREEMENT.** Unless otherwise specified, this Agreement embodies the entire understanding between UC and the Sponsor for this project, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments, waivers, or changes to this Agreement, including without limitation, changes in the statement of work, total cost, and period of performance, shall be effective unless made in writing and signed by authorized representatives of the parties.

29. **NO WAIVER.** The failure of a party to exercise any right or to demand the performance by the other party of duties required under this Agreement shall not constitute a waiver of any rights or obligations provided for herein.
30. **COUNTERPARTS.** This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all counterparts put together shall constitute one and the same agreement.

By signature below of duplicate originals, Sponsor and UC hereby agree to this Sponsored Research Agreement as of the Effective Date.

**UNIVERSITY OF CINCINNATI**

By ___________________________  By ___________________________
Name  David S. Gearring  Name ___________________________
Title  Director, Grants and Contracts,  Title ___________________________
Sponsored Research Services
Date ___________________________  Date ___________________________
Tax ID No.  31-600989  Tax ID No.: __________________
DUNS No.  04106-4767  DUNS No.: __________________

I hereby affirm the representations set forth in the Debarment, Disqualification, and Conflict of Interest section of this Agreement, and the acknowledgements set forth in the Relationship section and the Compliance with Law sections of this Agreement.

Principal Investigator, Read and Understood:

By: ___________________________
Name: ___________________________
Date: ___________________________
Exhibit A
University of Cincinnati Approved Protocol

Protocol No. __________
Exhibit B
Budget (Per Patient Costs)
Office of General Counsel  
University of Cincinnati  
University Hall, Suite _____  
51 Goodman Drive  
Cincinnati, OH 45221-_____  

Re: Sponsor's Indemnification Statement  

University of Cincinnati IRB Number _______________________ (the "Study")  

To Whom it May Concern:  

The University of Cincinnati Institutional Review Board ("IRB") has agreed to review a proposal involving a study of the following drug(s) and/or device(s) _______________________________ (hereinafter "Study Article(s)" in human subjects. The Study Article(s) are described as follows: _______________________________. The study will be supported through financial or other support from _______________________________, a firm doing business in the United States ("Company").  

As a condition of having research on this drug or device reviewed by the University of Cincinnati IRB, the Company agrees to observe and abide by all of the policies and procedures of the IRB and all provisions of applicable law. In addition, Company agrees to indemnify, defend, and hold harmless the University of Cincinnati and its Board of Trustees, the University of Cincinnati IRB, the investigator(s) and any agents, servants or employees of the above (hereinafter the "Indemnitees") from and against any and all claims and lawsuits, and any resulting damages, liabilities, costs and expenses (including reasonable attorneys' fees) for injuries, losses or damages of any kind alleged to have been caused by or attributed to any subject's participation the Study or use of the Study Article(s) in the Study.  

The indemnification and hold harmless commitment shall not operate:  

1) If the University, Investigator(s), their agents, servants, or employees are shown not to have adhered to the written research protocol as approved by the University of Cincinnati IRB or not to have adhered to written directions furnished by the Company for use and administration of the Study Article(s), or  

2) If the Company is not promptly notified of a claim or suit.  

Company’s obligation hereunder shall be contingent upon the Indemnitees' cooperating fully in the handling of any claims and in the event of suit, attending hearings and trials and assisting in securing and giving evidence. Further, the indemnification and hold harmless commitment shall not cover any loss, damage or expense arising from the negligence or willful misconduct of any Indemnitee.  

In the event of a claim or lawsuit, notification should be addressed to:  

______________________________  
______________________________  
______________________________  

______________________________  

Authorizing Representative of Company (Signature)  

Title  

Version 03-2012
TO: Kyle E. Hern, JD  
Mail Location 0663

FROM: ________________________________  
_______________________________  
Signature of Principal Investigator

DATE:

RE: Waiver of Indemnification - IRB #: _______________________

Study title: _________________________________________________

Dear Mr. Hern:

Based on the following criteria, I am requesting a waiver of indemnification for the above-referenced study. (Check all that apply.)

___ Investigator initiated;

___ not intended to support significant changes in product labeling or advertising for the drug or device;

___ not intended to involve a route of administration, dosage level, use in a patient population or other factors that significantly increases the risks or decreases the acceptability of the risks associated with the drug or device;

___ not intended to be reported to the FDA as a well-controlled study in support of a new indication for the drug or device; and

___ not intended to commercialize the drug or device and meets requirements for institutional review and informed consent.

In addition, _________________ will provide funding and FDA-approved drug or device(s) to be administered within the dosage limits or indications approved by the FDA.

The drug or device company will not provide an indemnification statement or product liability statement.

Please contact _________________ at Phone: _________________, E:-mail_______________ if you require additional information.

By: ____________________________

Name: __________________________

Version 03-2012
Exhibit D
Payments to the University of Cincinnati

(MUST REFERENCE INVOICE NUMBER WITH PAYMENT WHEN APPLICABLE)

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<thead>
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<td></td>
<td>EMAIL REMITTANCE ADVICE:</td>
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<tr>
<td></td>
<td><a href="mailto:rhonda.bastian@uc.edu">rhonda.bastian@uc.edu</a></td>
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</tbody>
</table>

Questions? Contact Rhonda Bastian
Grant Administrator II
Sponsored Research Services - Accounting Division
513 556 4804
rhonda.bastian@uc.edu

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Internal Note:

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<th>Clinical Trials</th>
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<tbody>
<tr>
<td>University of Cincinnati</td>
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<tr>
<td>Enter Departmental Accounting or BA contact Info.</td>
</tr>
<tr>
<td>RE: _________________________</td>
</tr>
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</table>
Exhibit E
Federal Prime Award (If flow-through)