clinical trials Contract

THIS AGREEMENT effective this \_\_\_\_\_ of \_\_\_\_\_\_\_\_\_, 20\_\_, by and between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ("Sponsor") and The University of Iowa, Iowa City, Iowa, a non-profit educational institution ("University").

**WITNESSETH:**

WHEREAS, the Project contemplated by this Agreement is of mutual interest and benefit to University and to Sponsor and will further the instructional and research objectives of University in a manner consistent with its status as a non-profit, tax-exempt, educational institution;

NOW, THEREFORE, in consideration of the premises and mutual covenants herein contained, the parties hereto agree to the following:

**ARTICLE 1 - Project**

"Project" shall mean the activities described in the Protocol, attached hereto as Exhibit A and incorporated by reference herein, under the direction of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ as Principal Investigator.

**ARTICLE 2 - Effective Date and Term of Contract**

 Contract Period is \_\_\_\_\_\_\_\_\_\_, 20\_\_\_, through \_\_\_\_\_\_\_\_\_\_, 20\_\_\_.

**ARTICLE 3 - Performance**

3.1 University shall commence the performance of Project promptly after the effective date of this Agreement and institutional review board (IRB) approval, and shall use reasonable efforts to perform such Project substantially in accordance with the terms and conditions of this Agreement. Sponsor and University may at any time amend Project by mutual written agreement. University shall conduct the Project in accordance with the Protocol and all applicable federal regulations related to the conduct of clinical trials, including, but not limited to, such regulations promulgated by the United States Food and Drug Administration.

3.2 In the event that the Principal Investigator becomes unable or unwilling to continue Project, and a mutually acceptable substitute is not available, University and/or Sponsor shall have the option to terminate said Project.

**ARTICLE 4 - Costs, Billings, and Other Support**

4.1 It is hereto agreed and understood by the parties that, subject to Article 3, Sponsor shall pay the University the sum of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, (\_\_\_\_\_\_\_\_\_) Dollars in accordance with the payment schedule set forth in Exhibit B.

4.2 Checks shall be made payable to the University of Iowa and sent to:

 Grant Accounting Office

 B5 Jessup Hall

 The University of Iowa

 Iowa City, IA 52242

 The tax identification number for the University is 42-6004813.

4.3 For purposes of identification, each payment shall include Sponsor’s name, the title, the protocol number of the Project and the name of the Investigator. *Sponsor shall return a copy of the University invoice with each payment.*

4.4 University shall retain title to any equipment purchased with funds provided by Sponsor under this Agreement.

4.5 In the event of early termination of this Agreement by Sponsor pursuant to

Article 5 hereof, Sponsor shall pay all costs accrued by University as of the date of termination, as well as any non-cancelable obligations.

4.6 IRB Fees: Sponsor will reimburse reasonable IRB fees for the initial IRB review directly to the IRB. If a local IRB is used, Sponsor will reimburse Institution for reasonable IRB fees for the initial IRB review, not to exceed $2,000, upon receipt of documentation of IRB review and receipt of an invoice from the IRB. Sponsor will reimburse Institution for annual IRB review and/or Protocol amendments, as necessary. The Sponsor will send IRB fee payments to;

IRB Name; University of Iowa
 Human Subjects/IRB Office
 105 Hardin Library for the Health Sciences
 Iowa City, IA 52242-1098

**ARTICLE 5 - Term and Termination**

5.1 This Agreement shall become effective upon the date first hereinabove written and shall continue in effect for the full duration of the Contract Period unless sooner terminated in accordance with the provisions of this Article. The parties hereto may, however, extend the term of the Agreement for additional periods as desired under mutually agreeable terms and conditions that the parties reduce to writing and sign. Either party may terminate this Agreement upon ninety (90) days prior written notice to the other.

5.2 In the event that either party hereto shall commit any breach or default in any of the terms or conditions of this Agreement, and also shall fail to remedy such default or breach within ninety (90) days after receipt of written notice thereof from the other party hereto, the party giving notice may, at its option and in addition to any other remedies which it may have at law or in equity, terminate this Agreement by sending notice of termination in writing to the other party to such effect, and such termination shall be effective as of the date of the receipt of such notice.

5.3 Subject to Article 9, termination of this Agreement by either party for any reason shall not affect the rights procured and obligations incurred under this Agreement. No termination of this Agreement, however effectuated, shall affect the Sponsor's rights and duties under Article 9 hereof, or release the parties hereto from their rights and obligations under Articles 4, 6, 7, 8, 9, 10, 11, 12, 13 and 17.

**ARTICLE 6 - Publicity**

Sponsor shall not use the name of University, nor of any University employee in any publicity, advertising, or news release or in any way imply endorsement of the University without the prior written approval of an authorized representative of University. University shall not use the name of Sponsor, nor any employee of Sponsor, in any publicity without the prior written approval of Sponsor. University is free to disclose, without Sponsor’s approval, the terms of this Agreement that are a matter of public record under the Iowa Open Records Law, Iowa Code Chapter 22.

**ARTICLE 7 – Project Results/Publications/Presentations**

7.1 Sponsor agrees to provide University and Researchers with Project results that could affect the safety or medical care of subjects enrolled in the Project.

7.2 Sponsor recognizes that under University policy, the publication and/or presentation of research findings must be permitted and agrees that Researchers engaged in Project shall be permitted to present research results at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of Project, provided the Sponsor shall have been furnished copies of any proposed publication or presentation at least one (1) month in advance of the submission of such proposed publication or presentation to a journal, editor, or other third party. Sponsor shall have thirty (30) days, after receipt of said copies, to object to such proposed presentation or proposed publication because there is Confidential Information (as defined in Article 9 herein) of Sponsor that needs protection. In the event that Sponsor makes such objection with respect to protection of Confidential Information, said Researcher(s) shall refrain from making such publication or presentation for a maximum of six (6) months from date of receipt of such objection in order for University to file patent application(s) with the United States Patent and Trademark Office and/or foreign patent office(s) directed to the patentable subject matter contained in the proposed publication or presentation.

7.3 Notwithstanding the foregoing, to the extent that the University's participation in the Project is a part of a multi-center study, University and Principal Investigator agree to publish or publicly present their results only together with the other sites unless specific written permission is obtained in advance from Sponsor to publish separate results. Sponsor shall advise as to the implications of timing of the publication in the event clinical trials are still in progress at sites other than at the University.

7.4 The collaborative publication or presentation described in 7.3 above shall occur within nine months of the date of close of Study at all Study sites, or, University shall be free to publish its results separately at that time.

**ARTICLE 8 - Inventions and Patent Rights**

8.1 University will make reasonable efforts to secure from personnel assigned to this Project, disclosures of any and all inventions and improvements conceived or reduced to practice by said personnel in the performance of this Project. In the event these inventions and improvements are derived from work funded by federal funds, the Federal Government can exercise its right to a royalty-free license on each of these inventions and improvements. University shall retain all right, title and interest in and to such inventions and improvements and all patent applications it may file at its election.

8.2 In consideration of Sponsor support of this study, and subject to the rights set forth in 8.1, supra, University agrees to grant Sponsor an option for an exclusive license on any such invention(s) and improvement(s). This option will exist for six (6) months after University has informed Sponsor of the invention(s) or improvement(s). If Sponsor exercises its option, Sponsor and University shall negotiate in good faith toward mutually agreeable terms to a license agreement. These negotiations shall be concluded within three (3) months from the date Sponsor exercises its option, unless the time period is extended in writing by mutual agreement.

8.3 Rights to inventions, improvements, and/or discoveries conceived and/or made during the Contract Period of this Project, whether patentable or copyrightable or not, relating to the Project which are made jointly by University employees and Sponsor employees, shall be the joint property of University and Sponsor, subject to the terms and conditions of this Agreement.

8.4 All inventions or improvements conceived or first reduced to practice during the term of this Agreement by Sponsor shall be owned by Sponsor.

**ARTICLE 9 - Confidential Information**

9.1 It is the responsibility of the Sponsor to identify and mark in advance as confidential any information that it deems appropriate to share with the University ("Confidential Information"). The University shall have the right to accept or reject that information, but if such information is accepted it will be withheld by the University from publication, and in all other respects shall be maintained by the University as confidential and proprietary to Sponsor.

9.2 University (The University of Iowa, its agents, servants and employees) agrees, for a period of five (5) years following the date of this Agreement, to retain in confidence all Confidential Information of Sponsor which Sponsor has identified (if materials) and has marked (if documents) as confidential and has provided to University pursuant to the terms of this Agreement. University will not, without the written consent of Sponsor, use said Confidential Information supplied hereunder for any purpose other than that indicated herein. The obligation of nondisclosure does not apply with respect to any of the Confidential Information that: a) is or becomes public knowledge through no fault of University; b) is disclosed to University by a third party entitled to disclose such information; c) is already known to University as shown by prior written record; d) is necessary to obtain IRB approval of Project or must be included in the subject written information summary and/or informed consent form; e) is required to be disclosed by law or court order; or f) is requested of Investigator and/or Institution by the FDA or DHHS.

9.3 In the event it is necessary for University to provide to Sponsor any information relating to the medical condition or care of a study participant in a manner that identifies the subject, Sponsor agrees to maintain the confidentiality of that information.

9.4 No license or other right is created or granted hereby, except the specific right to conduct this Project as set forth by Protocol and under the terms of this Agreement, nor shall any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the parties duly signed by their authorized representatives.

**ARTICLE 10 – Subject Injury; Indemnification**

10.1 In consideration of the University conducting this Project, Sponsor agrees that, should any subject suffer injury or illness related to protocol-mandated procedures, including but not limited to the administration of the drugs or devices in accordance with the Protocol, Sponsor will reimburse the University for all hospital and medical costs required for diagnosis and treatment of such injury or illness.

10.2 Sponsor further agrees to defend, indemnify, and hold harmless The University of Iowa (including the investigators; Board of Regents, State of Iowa; Institutional Review Board; officers; agents and employees (collectively referred to as "Indemnitees"), from and against loss, damage, cost and expense of claims and suits seeking damage alleged to have been caused by or attributed to (1) Indemnitees in its/their testing and/or reporting the results of the testing and/or (2) the drug or device provided by Sponsor, identified in the Protocol, including the cost and expenses of handling said claims and defending said suits; provided, however, that (1) Indemnitees are shown to have adhered to and complied with all material and substantive specifications and directions set forth in the Protocol and written instructions furnished by the Sponsor for the use and administration of such drug or device, as well as all applicable regulations promulgated by the United States Food & Drug Administration or other regulatory agencies (with the exception of the regulations codified at 21 CFR 58 (GLP)) and (2) Sponsor is promptly notified in writing of any such claim or suit. Indemnitees agree to fully cooperate in the handling of any such claim, and in the event of suit to attend hearings and trials and assist in securing and giving evidence and in obtaining the attendance of necessary and proper witnesses. This agreement by Sponsor to indemnify, defend and hold harmless shall not extend to cover loss, damage or expense arising from negligence of Indemnitees.

**ARTICLE 11 - Insurance**

Sponsor agrees to maintain, throughout the term of this Agreement, sufficient liability insurance coverage, including coverage for product liability, with limits of not less than two million U.S. dollars (U.S.$2,000,000) per occurrence and two million U.S. dollars (U.S.$2,000,000) annual aggregate. Sponsor shall be solely responsible for any insurance deductible amounts and the University will not share such responsibility. Sponsor agrees to provide appropriate evidence to University of such coverage upon execution of this Agreement.

**ARTICLE 12 - Independent Contractor**

In the performance of all services hereunder:

12.1 University shall be deemed to be and shall be an independent contractor and, as such, University shall not be entitled to any benefits applicable to employees of Sponsor.

12.2 Neither party is authorized or empowered to act as agent for the other for any purpose and shall not on behalf of the other enter into any contract, warranty, or representation as to any matter. Neither shall be bound to the acts or conduct of the other.

12.3 Nothing in this Agreement shall be construed to limit the freedom of individuals participating in this study, whether paid under this Agreement or not, to engage in similar inquiries made independently under other grants, contracts or agreements with parties other than Sponsor.

**ARTICLE 13 - Financial Arrangements**

 Sponsor certifies that it has no financial arrangement with Principal Investigator whereby

 the value of any compensation to Principal Investigator could be influenced by the

 outcome of the Project.

**ARTICLE 14 - Warranties**

University makes no EXPRESS OR IMPLIED warranties, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, RELATED TO the results of this study. The University shall not be liable for any direct, consequential, or other damages suffered by Sponsor or any others as a result of this study.

**ARTICLE 15 - Assignment**

15.1 This Agreement shall not be assigned by either party without the prior written consent of an authorized representative of each of the parties hereto.

15.2 This Agreement is assignable to any division or subsidiary of Sponsor.

**ARTICLE 16 - Governing Law**

This Agreement shall be governed and construed in accordance with the substantive laws of the State of Iowa, without giving effect to its conflict of laws provisions.

**ARTICLE 17 - Agreement Modification**

Any agreement to change the terms of this Agreement in any way shall be valid only if the change is made in writing and approved by prior mutual agreement of an authorized representative of each of the parties hereto.

**ARTICLE 18 - Records**

18.1 University agrees to maintain adequate and accurate records as required under the Protocol. Records shall be accessible for inspection and copying by authorized representatives of Sponsor and the FDA at reasonable times and in a reasonable manner.

18.2 In the event this Project is terminated and/or upon completion, University agrees to return all documents and copies thereof and any other materials supplied to it by Sponsor pursuant to this Agreement that have been designated as Confidential Information by Sponsor, EXCEPT that University may retain one copy of any such document or other material in a secure location for purposes of identifying and satisfying its obligations under this Agreement. Such records shall be retained for at least three years after completion of the research.

**ARTICLE 19- Export Control**

The disclosing party agrees to share any export determinations when products, services and/or technical data under this Agreement are subject to export controls under U.S. Government export laws and regulations; however, each party will be solely responsible for compliance with U.S. Government export laws and regulations as those laws and regulations apply to its own activities under this Agreement.

**ARTICLE 20- Registration**

Sponsor agrees to comply fully with all applicable requirements relating to the registration of clinical trials set forth in Title VIII of the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85). Specifically, Sponsor acknowledges that it is the “responsible party” as that term is defined in Section 801(s)(2)(j)(1)(A)(ix) of the Act and that the Study is an “applicable clinical trial” as that term is defined in Section (801)(a)(2)(j)(1)(A)(i) thereof.

**ARTICLE 21- Notices**

Notices, invoices, and communications hereunder shall be given by registered or certified mail, or express delivery service, postage or delivery charge prepaid, and addressed to the party to receive such notice, invoice, or communication at the address given below, or such other address as may hereafter be designated by notice in writing. Notice shall be deemed made on the date of receipt.

If to Sponsor:

If to University: The University of Iowa

Division of Sponsored Programs

Attention:

2 Gilmore Hall

Iowa City, Iowa 52242

PH: 319/335-2123

FAX: 319/335-2130

If Technical Matter:

 For Payment Remittance:

 The University of Iowa

 Grant Accounting Office

 B5 Jessup Hall

 Iowa City, Iowa 52242-1316

 Phone: 319-335-3801

 Fax: 319-335-0674

IN WITNESS WHEREOF, the proper parties, duly authorized, have executed this Agreement in duplicate as of the day and year first written above.

SPONSOR THE UNIVERSITY OF IOWA

Name: Jennifer Lassner

Title: Executive Director

 Division of Sponsored Programs

Date: Date:

Rev. 03/30/2012