**Investigator Initiated Clinical Trial Agreement**

**THIS AGREEMENT** is entered into effective as of       (the “Effective Date”) by and between Regents of the University of Minnesota (the "University"), a public educational institution and a Minnesota constitutional corporation, and       (the “Sponsor”), a      . This Agreement is entered into by the University through its Office of Sponsored Projects Administration.

**WHEREAS,**       is a University employee, and shall act on behalf of University in performance of the Study as Sponsor Investigator (“Investigator”);

**WHEREAS**, University has received funding from Sponsor to conduct a research project involving human subjects under the Protocol entitled       conceived by University (“Study”) shown as Exhibit A to this Agreement and incorporated herein as specified;

**WHEREAS**, University has appropriate facilities and patient population to provide data for the Study; and

**WHEREAS**, the Study contemplated by this Agreement is of mutual interest and benefit to University and Sponsor, and will further the instructional and research objectives of University in a manner consistent with its status as nonprofit educational institution, and further the financial and business objectives of Sponsor;

**NOW, THEREFORE**, the parties agree as follows:

1. Study. The University agrees to conduct the Study in accordance with the Protocol which has been written by Investigator and approved by Sponsor.
2. Investigator. The Investigator is responsible for the overall conduct of the study at University. Investigator is the individual who both initiated and will conduct this clinical investigation in accordance with Title 21, Code of Federal Regulations, Part 312. If Investigator is unable to continue to serve in that role and a successor acceptable to both University and Sponsor is not available, this Agreement will be terminated in accordance with Section 6.
3. Study Device. Sponsor agrees to timely provide, at no cost, sufficient quantities of       (“Study Device”) to conduct the Study in accordance with the Protocol.
4. Study Budget. Compensation for this Study shall be on a fixed fee per procedure basis, including overhead, as outlined in the Budget attached hereto as Exhibit B and incorporated herein. Compensation to University may include startup costs as outlined in the Budget and incurred by University prior to execution of this Agreement. University may rebudget costs, within the total amount contracted under this Agreement, as necessary to conduct the Study.
5. Compliance with Laws and Regulations. Sponsor and Institution shall comply with and conduct all aspects of the Study in compliance with all applicable federal, state, and local laws and regulations, including generally accepted standards of good clinical practice as adopted by current FDA regulations and statutes and regulations of the U.S. Government relating to exportation of technical data, computer software, laboratory prototypes, and other commodities as applicable to academic institutions. Institution will only allow individuals who are appropriately trained and qualified to assist in the conduct of the Study.
6. Term and Termination.

6.1 The term of this Agreement shall commence upon the Effective Date and terminate upon the completion of the Parties’ Study-related activities under the Agreement, unless terminated early as further described in this Section.

6.2. Either party has the right to terminate the Study upon thirty (30) days prior written notice to the other party. This Study may be terminated immediately at any time for any reason by the Institution or Sponsor when, in their judgment or that of the Principal Investigator, the Institution’s IRB, Scientific Review Committee, if applicable, or the Food and Drug Administration, it is determined to be inappropriate, impractical, or inadvisable to continue, in order to protect the Study subjects' rights, welfare, and safety, or the IRB otherwise disapproves the Study. If for any reason Principal Investigator becomes unavailable to direct the performance of the work under this Agreement, Institution shall notify Sponsor. If the Parties are unable to identify a mutually acceptable successor, this Agreement may be terminated by either Party upon thirty (30) days written notice.

6.3. Notwithstanding the above, any Party may, in addition to any other available remedies, terminate this Agreement upon the other Party’s material default or breach of this Agreement, provided that the defaulting/breaching Party fails to remedy such material default, breach, or failure to adhere to the Protocol within thirty (30) business days after written notice thereof.

6.4. In the event that this Agreement is terminated prior to completion of the Study, for any reason, Institution shall furnish to Sponsor any required final report for the Study. Promptly following any such termination, Institution will provide to Sponsor copies of Data collected pursuant to the Study Protocol.

6.5. If this Study is terminated early by either Party, the Institution shall be reimbursed for all work completed, on a pro rata basis, and reasonable costs of bringing the Study to termination incurred through the date of termination, and for non-cancelable commitments properly incurred through that date. Upon receipt of notice of termination, Institution will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with Sponsor to provide for an orderly wind-down of the Study.

6.6 Paragraphs 11 through 20 shall survive any termination of this Agreement.

1. Institutional Review Board Approval. Investigator shall apply for approval to conduct the Study with University’s Institutional Review Board ("IRB"). University shall not initiate the Study until such approval is obtained, and University is provided with a final copy of the IRB approval letter for the Study. University’s obligation to conduct the Study is expressly conditioned upon the approval of its IRB. University shall cooperate with Investigator in preparing and filing the Protocol, informed consent form, and other required information with the IRB.
2. Data and Reporting.

8.1 University will submit progress reports as requested by Sponsor. Within one year of the conclusion or termination of the Study, University will submit a final Study report with de-identified Study data.

8.2 All Study data shall be the sole property of University. Except for (a) University’s right to control publication of its own research results subject to the provisions of Section 11 hereof, (b) patented and patent-pending University Inventions, and (c) University Confidential Information other than Study data, Sponsor shall have the right to use the de-identified Study data, progress reports and the final report prepared for Sponsor for any purpose subject to any applicable signed informed consent documents and authorization forms, applicable laws and terms of this Agreement.

1. HIPAA. The parties understand and agree that any use of disclosure of Protected Healthcare Information, as defined in the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA) shall be subject to the authorization provided by the research subject in the informed consent or other authorization document. In addition, University shall collect, use, store and disclose data and materials, including any biological safety samples, collected from Study subjects only as allowed by the informed consents, or other authorizations, obtained from such Study subjects. University shall maintain Study records for the period of time and in a secure fashion as required by applicable Good Clinical Practices, federal, state, local laws, regulations, including HIPAA, or guidance.
2. Publications.

10.1 Sponsor recognizes that under University policy the results of the Project must be publishable and agrees that researchers engaged in the Project shall be permitted to present 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 the Project. University shall have the final authority to determine the scope and content of any publication; provided, however, that University shall provide copies of any proposed publication at least thirty (30) days in advance of the publication or presentation to Sponsor to review and object to such publication or presentation because such draft either contains information deemed to be Confidential Information under the provisions of Section 11 of this Agreement, or reveals information that if published within thirty (30) days would have an adverse effect on a patent application in which Sponsor owns full or part interest, or intends to obtain an interest from University pursuant to this Agreement. In the event that Sponsor notifies the University in writing that the proposed publication or presentation contains Sponsor's Confidential Information, the University shall remove any Sponsor Confidential Information from the draft prior to such publication or presentation. In the event Sponsor requests in writing a delay in publication to file for patent protection, the University and the Researcher shall refrain from making such publication or presentation for a maximum of ninety (90) days from the receipt of such objection, and Sponsor shall indicate with specificity to what manner and degree University may disclose said information during the ninety (90) day period.

10.2 Publication by either party to this Agreement shall give proper credit to the other party for the cooperative character of the investigation.

10.3 No commercial brands or trade names shall appear in the publication of the results except as such brand or trade name is essential in the description of the research.

1. Confidentiality.

11.1 For purposes of this Agreement, "Confidential Information" means written or tangible information disclosed by either party to the other, which at the time of disclosure is clearly and conspicuously labeled “Confidential” or “Proprietary”. Confidential Information shall also include oral and visual disclosures which are identified as confidential at the time of such disclosures and which are confirmed and summarized within fifteen (15) days of the disclosure by the disclosing party in a writing that sets forth the substance of the Confidential Information disclosed. The Protocol shall be considered University’s Confidential Information regardless of being labeled as such. The parties agree to maintain confidentiality of the Confidential Information during the term of this Agreement, including any renewal periods, and for a period of three (3) years from the effective termination or expiration date of this Agreement. Neither party shall use said Confidential Information for any purpose other than those purposes specified in this Agreement. The parties may disclose Confidential Information to employees requiring access thereto for the purposes of this Agreement provided, however, that prior to making any such disclosures each such employee shall be apprised of the duty and obligation to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement. Neither party will be held financially liable for any inadvertent disclosure, but each will agree to use its reasonable efforts not to disclose any Confidential Information.

11.2 Nothing contained herein will in any way restrict or impair either party's right to use, disclose, or otherwise deal with any Confidential Information which:

11.2.1 At the time of its receipt, is generally available in the public domain, or thereafter becomes available to the public through no act of the receiving party;

11.2.2 Was independently known prior to receipt thereof, or made available to such receiving party as a matter of lawful right by a third party;

11.2.3 Is received without obligation of confidentiality from a third party; or

11.2.4 Is required by law (including the Minnesota Government Data Practices Act), and/or regulation or court order to be disclosed. In the event that Confidential Information is required to be disclosed pursuant to this subsection, the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under law.

1. Intellectual Property.

12.1 It is recognized and understood that certain existing inventions and technologies are the separate property of University or Sponsor and are not affected by this Agreement, and neither party shall have any claims or rights in such separate inventions. University agrees that any new patentable inventions, developments, discoveries resulting from the Study (“Inventions”) shall be promptly disclosed in writing to Sponsor. Any Inventions developed in the course of the Study conducted hereunder shall be owned by the party or parties whose employees make or generate the Invention, in accordance with the parties’ respective intellectual property policies and procedures. Jointly made or generated Inventions shall be jointly owned by the parties with inventorship determined in accordance with United States patent law.

12.2 Sponsor is hereby granted, without option fee other than consideration of the Study sponsored herein and the reimbursement to Institution for patent expenses incurred prior to or during the option period, an option to acquire an exclusive, worldwide, royalty bearing license to any Invention, which option shall extend for no more than ninety (90) days after Sponsor’s receipt of an Invention disclosure from Institution (“Option Period”). The Parties shall use their reasonable efforts to negotiate, for a period not to exceed ninety (90) days after Sponsor’s exercise of such option, a license agreement satisfactory to both Parties (“Negotiation Period”). In the event Sponsor fails to exercise its option within the Option Period, or the Parties fail to reach agreement on the terms of such license within the Negotiation Period, Institution shall have no further obligation to Sponsor under this Agreement with regard to the specific Other Invention.

12.3 Regardless of whether Sponsor acquires a license to an Invention, University retains an irrevocable, world-wide, royalty-free, non-exclusive right to use the Inventions for teaching, research and educational purposes. The University shall have the right to sublicense its rights under this section to one or more non-profit academic or research institutions.

1. Insurance and Indemnification.

13.1 Each party represents that it has and will continue to have at least the following levels of insurance or self-insurance during the term of this Agreement: (i) as to the University, Workers’ Compensation in statutory compliance with Minnesota State Law; and (ii) as to both parties, General Liability Insurance in an amount not less than one million dollars ($1,000,000) each claim/three million dollars ($3,000,000) each occurrence. University represents that the University and Principal Investigator have and will continue to have Professional Liability insurance in an amount not less than one million dollars ($1,000,000) each claim/three million dollars ($3,000,000) each occurrence. Sponsor represents that it has and will continue to have Product Liability insurance or self-insurance in an amount not less than one million dollars ($1,000,000) per claim/three million dollars ($3,000,000) per occurrence. Certificates of all insurance detailed above shall be furnished to the other party upon request.

13.2 Each party shall be responsible for its own acts and the results thereof and not for the acts of the other party. Liability of the University is subject to the terms and limitations of the Minnesota Tort Claims Act, Minnesota Statutes Section 3.736.

13.3 Sponsor shall indemnify, defend, and hold harmless University against any and all claims, costs, or liabilities, including attorneys' fees and court costs at both trial and appellate levels, for any loss, damage, injury, or loss of life (other than that attributable to willful, wanton or intentional acts or omissions of the University) arising out of use by Sponsor or any third party acting on behalf of or under authorization from Sponsor of information, reports, discoveries, deliverables, materials, products or other results of University’s work under this Agreement. Article 11.3 shall apply with the provision that (a) University promptly notifies Sponsor in writing after University receives notice of any claim, (b) Sponsor is given the opportunity, at its option, to participate and associate with University in control, defense, and trial of any claim and any related settlement negotiations and (c) University fully cooperates with Sponsor in the defense of any such claim.

1. Disclaimer of Warranties. University makes no warranties, express or implied, as to any matter whatsoever, including without limitation, the condition, originality or accuracy of the research or any invention (s) or product(s), whether tangible or intangible, conceived, discovered, or developed under this agreement; or the ownership, merchantability, or fitness for a particular purpose of the research or any such invention or product.
2. LIMITATION OF LIABILITY FOR BREACH OF CONTRACT. IN NO EVENT SHALL EITHER PARTY’S LIABILITY FOR BREACH OF CONTRACT INCLUDE DAMAGES FOR WORK STOPPAGE, LOST DATA, OR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFIT), OF ANY KIND. THE UNIVERSITY’S LIABILITY TO SPONSOR FOR BREACH OF THIS AGREEMENT SHALL NOT EXCEED THE MONETARY CONSIDERATION PAID TO THE UNIVERSITY UNDER THIS AGREEMENT. EXCEPT FOR SPONSOR’S INDEMNIFICATION OBLIGATIONS UNDER SECTION 14, SPONSOR’S LIABILITY TO THE UNIVERSITY FOR BREACH OF THIS AGREEMENT SHALL NOT EXCEED THE MONETARY CONSIDERATION DUE UNDER THIS AGREEMENT.
3. Debarment. The University certifies that it has not been debarred under the provisions of the Generic Drug Enforcement Act of 1992 (the “Act”), and that it will not use in any capacity, in connection with the research activities to be performed under this Agreement, any individual who has been debarred pursuant to the Act.
4. Export Controls. The parties acknowledge that their activities may be subject to export control laws and regulations, including, without limitation, the Export Administration Regulations (15 CFR Parts 730-774) (“EAR”), the International Traffic in Arms Regulations (22 CFR Parts 120-130) (“ITAR”), and the Foreign Assets Control Regulations (31 CFR Parts 501-598). Except as provided in the following paragraph, each party will be solely responsible for its compliance with such export control laws and regulations. Before transferring any commodity, software, or technical data (collectively, “Items”) subject to the EAR or ITAR to University, Sponsor must first give notice to University that it intends to transfer the Items in question. Such notice shall identify the relevant classification on the Commerce Control List (for EAR Items) or category of the U.S. Munitions List (for ITAR Items). University shall have the right to decline receipt of Items subject to the EAR or ITAR. If University cannot reasonably conduct the Study without the controlled Items, the Agreement may be terminated by either party in accordance with Article 7. Sponsor shall not transfer Items subject to the EAR or ITAR to University until University has furnished written confirmation that it (a) will accept the Items, and (b) either has implemented a technology control plan or has determined that one is not needed.
5. Publicity.

18.1 Sponsor will not use the name, logos and other marks and trade names of University, nor of any

member of University’s Project staff, in any publicity, advertising, or news release without the prior

written approval of an authorized representative of University. University will not use the name, logos

and other marks and trade names of Sponsor, nor any employee of Sponsor, in any publicity without the

prior written approval of Sponsor.

18.2 Pursuant to the University’s Openness in Research Policy (a copy of which may be found at

http://www1.umn.edu/regents/policies/academic/Openness\_in\_Research.pdf) the University shall be

allowed to disclose the following non-confidential information without the approval of the Sponsor: (1)

the existence of the contract or grant; (2) the identity of the Sponsor or the grantor and, if a subcontract

is involved, the identity of the prime contractor if the results of the research must be reported to the

sponsor, grantor, or prime contractor; and (3) the purpose and the scope of the proposed research. The

University may also disclose information as needed to comply with institutional reporting requirements,

conflict of interest reviews, or in sponsored projects proposals or award documents (e.g., list of current

and pending support.)

1. Modification. Any alteration, modification, or amendment to this Agreement must be in writing and signed by both parties. No changes in the Protocol will be made unless agreed upon by University and the Investigator and approved by the IRB, or if it necessary to protect the safety, rights, or welfare of the Study subjects.
2. Assignment and Subcontracting. This Agreement may not be assigned by either party without the prior written consent of the other. In the event of an assignment of its rights hereunder in law or in fact, Sponsor agrees to provide at least thirty (30) notice in advance, and this Agreement shall be binding upon Sponsor, and its successors and assigns, if any. University may subcontract with subsites and will execute a written agreement with subsites obligating them to comply with relevant terms and conditions of this Agreement.
3. Independent Contractor. University's relationship to Sponsor under this Agreement shall be that of an independent contractor and not an agent, joint venturer, or partner of University.
4. Notice. Notices, requests, invoices, or communications, hereunder shall be deemed made upon submission to an overnight courier service or priority United States Mail, or three days after mailing by United States, first-class mail, certified or registered, postage 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:

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| If to Sponsor:  (Insert Contact Information and Address) | Name:  Address:      Telephone:  Fax:  E-Mail: |
| If to University:  (Insert Name) | Name:  Sponsored Projects Administration  University of Minnesota  450 McNamara Alumni Center  200 Oak Street S.E.  Minneapolis, MN 55455-2070  Telephone: (612)  Fax : (612)  E-Mail:      @umn.edu |
| with a copy to Principal Investigator  (Insert Contact Information) | Name:  Address:      Telephone:  Fax:  E-Mail: |

1. Entire Agreement. This Agreement and its attached Exhibits represent the entire understanding between the parties, and supersedes all other agreements, express or implied, between the parties as to its subject matter. Any alteration, modification, or amendment to this Agreement must be in writing and signed by both parties. In the event of conflict between the terms of the Protocol and this Agreement, the terms of the Protocol shall govern all medical and scientific matters, and the terms of this Agreement shall govern all other matters.
2. Force Majeure. If either party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such party’s direct control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather or other reason beyond the party’s control (a “Disability”) then such party’s performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Study budget shall be adjusted to account for cost increases or decreases resulting from the Disability. The party affected by the Disability shall notify the other party of such Disability as provided for herein.
3. Execution. This Agreement may be signed in counterpart by the parties and the Investigator, and together shall serve as the final, agreed-upon representation of their respective assent to its terms. Each party may execute this Agreement in portable document format, which shall constitute their assent to its terms.
4. Governing Law. Any action brought against the University shall only be brought in the courts of Hennepin County, Minnesota, USA, without regard to conflict of laws principles.

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**IN WITNESS WHEREOF**, the undersigned have executed this Agreement as of on the date first written above.

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| **REGENTS OF THE**  **UNIVERSITY OF MINNESOTA**    Name  Title:  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **SPONSOR**    Name  Title:  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

I have read the above agreement and agree to perform my obligations as principal investigator(s) under this agreement. I also understand and agree to the disposition of rights in inventions, discoveries, and other results as provided by this agreement and to the provisions concerning confidentiality and publications. I will inform students and other participants working on this research of their rights and obligations under this agreement.

Principal Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

**Exhibit A**

**Protocol**

**Exhibit B**

**Costs, Billings, and Other Support**