

## CLINICAL TRIAL AGREEMENT

This Agreement is entered into on \_\_\_\_\_ by and between \_\_\_\_\_ (“Sponsor”), a \_\_\_\_\_ established under the laws of \_\_\_\_\_, with offices located at \_\_\_\_\_ and the University of Rochester (“Institution”), a not-for-profit educational institution established under the laws of New York State, with business offices located at 5<sup>th</sup> floor Hylan Building, RC Box 270140, Rochester, NY 14627.

### RECITALS

Whereas, Sponsor desires Institution to study the safety and/or efficacy of \_\_\_\_\_ (“Study Drug”) or (“Study Device”) and Institution is willing to perform a clinical study of the Study Drug/Device; and

Whereas, the Study (as defined below) is of mutual interest and benefit to Sponsor and Institution, and will further the Institution’s instructional and research objectives in a manner consistent with its status as a not-for-profit tax-exempt educational institution;

Now therefore, in consideration of the promises and mutual covenants herein contained, Sponsor and Institution hereby agree as follows:

1. **STATEMENT OF WORK.** The Institution shall exercise reasonable efforts to carry out the clinical research study set forth in the research protocol developed by the Sponsor dated \_\_\_\_\_ and entitled \_\_\_\_\_ (the “Study”), which is attached hereto as Exhibit A (the “Protocol”) and hereby incorporated into this Agreement by reference. The Study shall be conducted under direction of \_\_\_\_\_ “Principal Investigator” in accordance with this Agreement.

In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. Changes in the Protocol may be made only through prior written agreement between the Sponsor and the Institution.

2. **PERIOD OF PERFORMANCE.** The Period of Performance under this Agreement shall be \_\_\_\_\_ through \_\_\_\_\_, unless extended by amendment of this Agreement or terminated in accordance with Article 14. The Study may not begin, and no patient shall be enrolled, until approval of the Study is received from the Institution’s Institutional Review Board (“IRB”).
3. **PAYMENT.**
  - (a) Sponsor shall reimburse the Institution for all direct and indirect costs incurred by Institution in accordance with the budget attached hereto as Exhibit B and incorporated herein by reference (the “Budget”). The parties estimate that the payments provided for in

the Budget will be sufficient to support the Study, but Institution may submit to Sponsor a revised budget requesting additional funds in the event that costs may reasonably be projected to exceed the Budget. Except as otherwise provided in this Agreement, Sponsor will not be required to make any payment in excess of the Budget without Sponsor's prior written approval.

The parties estimate that the costs set forth in the Budget are adequate to support the Study, but if certain patient care costs are expected to be covered by insurance or another third party payor and such costs are denied, Sponsor agrees to reimburse Institution for the patient care costs not covered by insurance or third party payors.

Regardless of whether it is included in the Budget, the Sponsor understands and agrees that it is responsible for paying the Institution's nonrefundable Institutional Review Board fee, and shall pay such fee within thirty (30) days of the date of invoice except as otherwise provided in the Budget.

(b) Sponsor shall make payments to Institution in accordance with the payment schedule set forth in Exhibit B and incorporated herein. Checks shall be made payable to the University of Rochester and sent to:

University of Rochester  
\_\_\_\_\_  
601 Elmwood Avenue, Box \_\_\_\_  
Rochester, NY 14642  
ATTN: \_\_\_\_\_

c) For purposes of identification, each payment shall include the title of the project and the name of the Principal Investigator.

4. SUPPLIES. Sponsor will provide Institution, at no charge, with a sufficient quantity of the Study Drug <or Device> to conduct the Study, as well as any other compounds, materials, equipment, and information, which the Protocol specifies, or which Sponsor deems necessary to conduct the Study. All such Study Drug <or Device>, compounds, materials, and equipment remain the sole property of Sponsor, unless otherwise designated.

5. INVESTIGATOR'S AND SPONSOR'S ASSURANCE.

(a) The Study shall be conducted in accordance with the Study Protocol, Sponsor's written instructions and all laws and regulations applicable to the performance of the Study. In the event that Sponsor's written instructions are inconsistent with the Protocol, the Protocol approved by the IRB shall take precedence.

(b) Institution, Principal Investigator and Sponsor shall comply with all applicable federal, state and local laws, regulations and guidelines including, but not limited to, the Federal Food, Drug and Cosmetic Act, as amended (the "Act") and regulations promulgated thereunder and the United States Food and Drug Administration ("FDA") regulations governing the protection of human subjects and regulations governing clinical investigators.

(c) Sponsor acknowledges that the responsibility to comply with and perform the provisions of 21 C.F.R. 312 subpart D and/or 21C.F.R. 812 Subpart C (Responsibility of Sponsors) rests with the Sponsor as required by FDA.

(d) Institution certifies that neither Institution nor any person employed or engaged by Institution in the conduct of the Study has been debarred pursuant to Sections 306(a) or (b) of the Act and that no debarred person will in the future be employed or engaged by Institution in connection with conduct of the Study. Institution further certifies that it will notify Sponsor immediately in the event of any debarment or threat of debarment of any person employed or engaged by Institution in the conduct of the Study occurring during the period of this Agreement.

(e) In connection with research studies, Institution may collect “Protected Health Information” (“PHI”) as defined in 45 C.F.R. Section 164.501 or medical information on a patient as defined under New York State Public Health Law. Institution shall obtain a patient authorization/informed consent from study subjects to allow Institution to disclose the PHI and medical information to Sponsor. Sponsor shall use the PHI or medical information in accordance with the patient authorization/informed consent. If either party de-identifies PHI in accordance with the standards set forth in 45 C.F.R. Section 164.514, either party may use and disclose the de-identified information as permitted by law.

6. NOTICES. Any notices related to this Agreement or required herein shall be in writing and delivered by first class mail, postage prepaid, or by facsimile to the parties as follows:

INSTITUTION

Gunta J. Lidars,  
Associate VP for Research Administration  
University of Rochester  
Office of Research & Project Administration  
5<sup>th</sup> Floor Hylan Bldg., Box 270140  
Rochester, NY 14627  
Phone: (585) 275-4031  
Fax: (585) 275-9492

SPONSOR

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

7. INDEPENDENT CONTRACTOR. The Institution is an independent contractor and not an agent, joint venturer, or partner of Sponsor.

8. INDEPENDENT RESEARCH. Nothing in this Agreement shall be construed to limit the freedom of the Principal Investigator and/or Institution, its employees and agents, 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.

9. CONFIDENTIAL INFORMATION. All information designated at the time of disclosure, in writing, by either party as confidential (“Confidential Information”) shall not be used by the other party other than for purposes of this Agreement. Each party agrees to treat

Confidential Information received from the other party with the same degree of care with which it would treat its own Confidential Information of a similar nature and further agrees not to disclose such Confidential Information to a third party without prior written consent of the other party, for a period of three (3) years following disclosure.

The foregoing obligations of non-disclosure do not apply to Confidential Information which:

- (a) is in the public domain at the time of disclosure or becomes publicly available through no fault of the recipient;
- (b) was known to the other party prior to disclosure;
- (c) was received from a third party not under an obligation of confidence to Sponsor;
- (d) is developed by the recipient without reference to the Confidential Information; or
- (e) is required to be disclosed by law.

Sponsor permits Institution to provide study-related documents (for example, the study protocol) to a third party insurance company, if required by an insurance company for the purpose of obtaining a benefit coverage determination on behalf of a patient requesting coverage for participation in a clinical study.

In addition, no Confidential Information involving individual patient data or medical records may be disclosed by either party at any time without appropriate patient authorization or consent as required by law.

10. DATA OWNERSHIP and INTELLECTUAL PROPERTY. (a) Sponsor shall retain ownership of all completed case report forms and data generated as a result of the Study. Institution shall have the right to maintain a copy of all Study data for educational, auditing, archival, patient care and/or research purposes and to use Study results for publication purposes as outlined in Article 11. All other original records of work completed under this Agreement including patient medical records, laboratory records and reports, scans, films and information pre-existing in Institution's databases shall be and remain Institution's property.

(b) If biological materials will be used or obtained in the performance of the Study, Sponsor agrees to reimburse Institution for the cost of shipping such biological materials to Sponsor. The term "biological materials" shall include the materials derived from subjects enrolled in the Study and used pursuant to the approved Protocol, including, but not limited to, blood, bone marrow, urine, sera and other human tissue or fluids. At no time shall any biological materials be used by Sponsor for any purpose other than as described in the Protocol or transferred to any third party without Institution's prior written consent. Upon completion or termination of the Study, all unused biological materials shall be destroyed as required under any law or regulation or stored as permitted by the Protocol and applicable law and regulation.

(c) Institution understands and acknowledges that the Study (Drug/Device) that is being provided to Institution for the purpose of conducting this Study is the property of Sponsor and/or that the Study (Drug/Device) is subject to certain intellectual property rights

owned by or licensed to Sponsor. This Agreement shall not be deemed or construed to convey or transfer any rights with respect to the Study (Drug/Device) or with respect to any of such existing intellectual property rights to Institution except insofar as necessary to permit Institution to conduct the Study which is the subject of this Agreement.

(d) For all purposes herein, "Invention" shall mean any discovery, improvement, concept or idea which arises out of work performed pursuant to the Study and which involve the use of the Sponsor's drug/device.. Institution Inventions shall be the sole and exclusive property of Sponsor. Institution will disclose promptly to Sponsor any and all Institution Inventions, patentable or not, arising out of the work pursuant to the Study and complete any paperwork necessary to vest title in such Invention in the Sponsor.

- 10A. DATA OWNERSHIP and INTELLECTUAL PROPERTY (for Investigator Initiated studies only)** Institution shall retain ownership of all completed case report forms and data generated as a result of the Study; however Sponsor shall have the right to use all data and results generated during the course of the Study for any Study related purpose.

Institution understands and acknowledges that the Study (Drug/Device) that is being provided to Institution for the purpose of conducting this Study is the property of Sponsor and/or that the Study (Drug/Device) is subject to certain intellectual property rights owned by or licensed to Sponsor. This Agreement shall not be deemed or construed to convey or transfer any rights with respect to the Study (Drug/Device) or with respect to any of such existing intellectual property rights to Institution except insofar as necessary to permit Institution to conduct the Study which is the subject of this Agreement.

For all purposes herein, "Institution Invention" shall mean any discovery, improvement, concept or idea which arises out of work performed pursuant to the Study, including processes, methods, formulae, and techniques. Institution Inventions shall be the sole and exclusive property of Institution. Institution will disclose promptly to Sponsor any and all Institution Inventions, patentable or not, arising out of the work pursuant to the Study and give Sponsor the first option to acquire an exclusive, worldwide, royalty-bearing license to the rights of Institution Invention. This option will expire six (6) months after the Institution's disclosure of the Institution Invention to the Sponsor.

- 11. PUBLICATION.** Sponsor acknowledges that Institution is dedicated to the generation of new knowledge and information and to its public dissemination. Therefore, Institution shall have the right to publish material resulting from or related to the Study. The Institution shall furnish Sponsor with a copy of any proposed written publication or presentation of such material at least thirty (30) days prior to the submission for publication or presentation. Sponsor may review the publication or presentation to see if it contains patentable subject matter or other Sponsor-owned confidential information that needs protection. Institution will, upon written request from Sponsor within the thirty (30) day review period, delay the publication or presentation for a maximum of an additional sixty (60) days to allow Sponsor or Institution to file a patent application or to remove the confidential information. Such Sponsor required modification will not result in withholding any study results from academic publication.

If this is a multicenter Study, Principal Investigator understands that it is the intention of the Sponsor that a multicenter publication will be prepared and published. Principal

Investigator understands and agrees not to publish the results of Institution's participation in the Study until after the completion of the Study at all participating sites and the review, analysis and write-up of the Study results. Should a multicenter publication not be prepared for submitted within 12 months after the Study is completed (e.g. the data is locked) at all participating sites, Principal Investigator may publish and present the individual Study results as stated in the preceding paragraph. If Sponsor elects to publish the results from Institution's participation, Sponsor agrees to provide Institution with a copy of the proposed publication at least thirty (30) days prior to publication and agrees to acknowledge Institution's participation in the Study as appropriate for peer review publications.

12. SITE ACCESS. Either Sponsor or FDA, as required by FDA regulations, shall have reasonable access to Principal Investigator and other project personnel, project facilities, drug records, subject records, case reports, and other records directly related to this Study, subject to applicable laws and regulations, during regular business hours and with reasonable prior notice.

If there is an FDA audit or investigation, Institution agrees to provide Sponsor with prompt notice of the audit or investigation and Sponsor may be present during such audit but Sponsor agrees not to alter or interfere with any documentation or practice of Institution. Institution shall be free to respond to any FDA inquiries and will provide Sponsor with a copy of any final response or documentation to the FDA regarding the Study. Sponsor agrees to reimburse Institution for the reasonable costs incurred by Study personnel in responding to an FDA audit or investigation.

13. PUBLICITY. Neither party shall use the name of the other in connection with any products, promotion, or advertising related to this Study without the prior written permission of the other party. The foregoing shall not, however, preclude any legally required disclosure, reports generated in the normal course of business, or acknowledgement of sponsorship as required by an academic organization.
14. TERMINATION. This Agreement may be terminated by either party for any reason upon thirty (30) days prior written notice to the other party. This Study may be terminated 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, or the Food and Drug Administration it is determined to be inappropriate, impractical, or inadvisable to continue. The Institution shall be reimbursed for the reasonable costs of bringing this Study to termination incurred prior to termination and for non-cancelable commitments outstanding at that date. The Sponsor shall receive a refund of any amounts paid prior to such termination in excess of amounts earned by the Institution as of the date of termination or notification of the decision to terminate, whichever is later. If a subject discontinues his or her participation or if the Study is discontinued for any reason, the Institution shall be held harmless and Sponsor shall pay Institution on a prorated basis for such subjects or as otherwise set forth in payment schedule.

All provisions of this Agreement that by their terms require performance by one or both parties following expiration or termination of this Agreement shall survive such expiration or termination. Such provisions shall include, but not be limited to, Articles, 3, 5, 6, 9, 10, 11, 12, 15, 17, 18, and 19.

15. INDEMNIFICATION.

(a) Sponsor shall indemnify, defend and hold harmless the Institution and its agents, representatives, trustees, officers and employees (“Indemnitees”) from and against any liability, damages, loss, expense, claims or costs that may be made or instituted against any of them (including the reasonable attorneys’ fees and other costs and expenses of defense), by reason of personal injury (including but not limited to death) or property damage which arises out of or is connected with the performance of the Study or use of the Study results or data; provided, however, that Sponsor shall not be liable for any loss or damage resulting from an Indemnitee’s (a) failure to adhere to the material terms of the Protocol; (b) breach of any applicable FDA or other government law or regulation; and/or (c) negligence or willful misconduct. Institution agrees to reasonably cooperate in the defense of any such action or claim.

Institution will promptly notify Sponsor of any such claim and will cooperate with Sponsor in the defense of the claim. Sponsor agrees, at its own expense, to provide attorneys reasonably acceptably to Institution to defend against any claim with respect to which Sponsor has agreed to provide indemnification hereunder. The Sponsor agrees not to settle any claim against the Institution with an admission of liability against the Institution without the Institution’s prior written consent. This indemnity shall not be deemed excess coverage to any insurance or self-insurance Institution may have covering a claim.

(b) Sponsor agrees to reimburse Institution for the cost of reasonable and customary medical treatment of any illness or injury sustained by a Study subject as a result of injuries or adverse reactions caused by the Study drug/device or for injuries caused by the administration of the Study drug or use of the Study device or adverse reactions directly related to the study or properly performed procedures in accordance with the Protocol, except to the extent that such costs are covered by subject’s insurance or other third party coverage. Notwithstanding the foregoing, Sponsor’s obligations under this paragraph shall not apply to the extent that any such cost or illness or injury is attributable to (i) the failure of Institution or Principal Investigator or other Institution personnel involved in the Study to adhere to the terms of the Study Protocol or to comply with applicable laws or regulations; (ii) any negligence or intentional misconduct of Institution, Principal Investigator or other Institution personnel involved in the Study; or (iii) the natural progress of the Study subject’s underlying disease.

**(If Sponsor requires indemnification from Institution)**

(c) Institution hereby agrees to indemnify, defend and hold harmless Sponsor, its respective agents, representatives, officers and employees (“Indemnitees”) from any liability, damage, loss or expense (including the reasonable attorneys’ fees and other costs and expenses of defense), by reason of personal injury or property damage which arises out of or connected with the negligence or intentional misconduct of Institution in performing the Study or the breach of any law or regulation applicable to Institution in the conduct of the Study, except to the extent that such liability is due to the negligence of Sponsor’s Indemnitees or breach of any law or regulation by Sponsor’s Indemnitees.

The Sponsor will promptly notify Institution of any such claim and will cooperate with the

Institution in the defense of the claim. Institution agrees, at its own expense, to provide attorneys reasonably acceptably to Sponsor to defend against any claim with respect to which the Institution has agreed to provide indemnification hereunder. Institution agrees not to settle any claim against Sponsor with an admission of liability against the Sponsor without Sponsor's prior written consent. This indemnity shall not be deemed excess coverage to any insurance or self-insurance the Sponsor may have covering a claim.

The provisions of this clause shall survive termination of this Agreement.

16. INSURANCE. (a) Sponsor shall, at its sole cost and expense, procure and maintain comprehensive liability, clinical trial and product liability insurance in amounts not less than \$3,000,000 per incident <and \$9,000,000 annual aggregate>. Such liability insurance shall include Institution and its trustees, directors, employees and agents as additional insureds with respect to this Agreement. If Sponsor's insurance is written on a claims made basis as opposed to an occurrence basis, Sponsor shall purchase tail coverage and/or a retrospective coverage provision to provide continuation and uninterrupted coverage of all claims. Sponsor's insurance will be primary coverage with respect to its indemnification obligations hereunder and Institution's insurance or self-insurance will be excess and noncontributory. Upon request, Sponsor shall provide Institution with written evidence of such insurance prior to commencement of the Study. Sponsor shall provide Institution with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance; if Sponsor does not obtain replacement insurance providing comparable coverage within such fifteen (15) day period, Institution shall have the right to terminate this Agreement effective at the end of such fifteen (15) day period without notice of any additional waiting periods.
- (b) Institution shall maintain Worker's Compensation insurance or other coverage on its employees as required by New York law and will self-insure or maintain insurance covering its liability under this Agreement.
- (c) Sponsor and Institution hereby waive any rights of subrogation.
17. COMPLIANCE WITH HIPAA. It is understood and agreed that Institution, as a covered entity under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), may not use or disclose protected health information ("PHI"), as defined in HIPAA and its implementing regulations, for purposes other than treatment, payment, or health care operations without first obtaining authorization from the individual concerned. Institution agrees to obtain authorization from individuals enrolled in the Study which permits disclosure to and use of PHI by Sponsor for purposes of conducting and overseeing the trial. Sponsor agrees that it shall not disclose PHI to any person or entity except as permitted by the HIPAA authorization.
18. COMMUNICATION CONCERNING CERTAIN EVENTS AFFECTING RESEARCH SUBJECTS. Sponsor acknowledges that Institution has a human research protection program that complies with the standards of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). In further of Institution's compliance with AAHRPP standards, Sponsor, Principal Investigator and Institution agree as follows:

Sponsor agrees to report as soon as practical to the Institution and the IRB any findings obtained from on-site monitoring activities or from study results obtained from this Study

that could be reasonably expected to (i) adversely affect the safety or medical care of a study subject or a study subject's willingness to continue to participate in the Study, or (ii) alter the conduct of the study or the IRB's determination of whether or how the Study should be conducted. The Sponsor will cooperate with the IRB in any determination made by an IRB on how any reported information would alter the Study or change the communication to study subjects.

The Sponsor shall promptly notify Institution within ten (10) business days of any findings of (1) new and unexpected serious adverse events arising from the Sponsor's monitoring of the Study that could affect the safety of study subjects, and (2) any new trends or patterns of non-serious or expected adverse events that occur at a specificity or severity that is inconsistent with prior observations, all as may be required by 21 CFR 312.32(c), 21 CFR 312.55(b) and 21 CFR 56.108(b). FDA's Guidance on Adverse Event Reporting to Institutional Review Boards in Clinical Trials (January 2009) may be used in meeting this requirement

The provisions of this Section shall survive for two years after termination of this Agreement.

19. NO WARRANTIES. THE INSTITUTION MAKES NO WARRANTIES, EXPRESS, OR IMPLIED, CONCERNING ANY MATTER WHATSOEVER, INCLUDING WITHOUT LIMITATION, THE RESULTS OF THIS STUDY OR THE OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF SUCH RESULTS. The Institution shall not be liable for any indirect, consequential, or other damages suffered by Sponsor or any other entity or individual including, but not limited to, damages arising from loss of data or delay or termination of the Study or from the use of the results of the Study or any invention or product resulting from the Study.
20. NO WAIVER. The waiver of any breach or default hereunder by either party shall not operate or be construed as a waiver of any repetition of such breach or default or of any other breach or default.
21. DISPUTES. If a dispute arises out of or relates to this Agreement, or breach thereof, the parties agree first to try in good faith to settle the dispute by negotiation, before resorting to arbitration, litigation, or some other dispute resolution procedure. The forum for such proceedings will be Monroe County, New York.
22. ENTIRE AGREEMENT. This Agreement describes the entire agreement between the parties concerning the subject matter hereof and supersedes all prior or contemporaneous agreements, representations or understandings, written or oral. This Agreement controls over any inconsistent agreement between Sponsor and Principal Investigator, and may not be amended, changed or modified except in a writing signed by both parties hereto.
23. ASSIGNMENT. Neither party may assign this Agreement without the prior written consent of the other party; provided, however, that Sponsor may assign this Agreement to a successor in ownership of at least 51% of its assets, provided that such successor expressly assumes, in writing, the obligation to perform in accordance with the terms and conditions of this Agreement. Any attempt by either party to assign this Agreement without such consent shall be void.

- 24. COUNTERPARTS. This agreement may be executed and delivered in one or more counterparts, which when executed and delivered shall be deemed to be an original but all of which when taken together shall constitute one and the same Agreement. A facsimile transmission or PDF file of this signed Agreement bearing a signature on behalf of a party shall be legal and binding on such party; however, this shall not preclude either party from requiring the exchange of original signatures.
- 25. SEVERABILITY. If any provision of this Agreement shall be or become invalid under any provision of federal, state or local law, or by a court of competent jurisdiction, such invalidity shall have no effect on the validity or enforceability of the remaining provisions of this Agreement, and they shall continue in full force and effect. If such deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the Agreement to give effect to the original intent of the parties.
- 26. GOVERNING LAW. This Agreement shall be interpreted in accordance with, and governed by, the laws of the State of New York, without regard to its conflict of laws rules, and irrespective of the domicile or residence of the parties or of the location of any property affected hereby. The venue for any action to interpret or enforce this Agreement shall be in Monroe County, New York.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate by proper persons thereunto duly authorized.

SPONSOR

UNIVERSITY OF ROCHESTER

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: Gunta J. Lidars

Title: \_\_\_\_\_

Title: Associate VP for Research Administration

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Read and Acknowledged:

I have read the foregoing and, while not a party to this Agreement, I understand and agree to comply with the obligations of the Principal Investigator as stated herein.

By: \_\_\_\_\_  
PRINCIPAL INVESTIGATOR

Name: \_\_\_\_\_

Date: \_\_\_\_\_