**MASTER CLINICAL RESEARCH AGREEMENT**

This **MASTER CLINICAL RESEARCH AGREEMENT** (“**Agreement**”)is entered into as of DATE (“**Effective Date**”) by and between \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ a corporation having it’s principal place of business at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(“**Sponsor**”) and the University of Rochester (“**Rochester**”), a non-profit educational institution and a body having corporate powers under the laws of the State of New York of the United States of America with business offices located at 500 Joseph C. Wilson Blvd.,, Rochester, New York 14627.

**RECITALS**

Rochester, through the faculty, students and personnel of its various departments, has valuable experience, skill and ability in a wide array of fields of clinical research.

Sponsor desires to have Rochester undertake such clinical research projects as are described in each various individually executed Statement of Works (“**SOWs**”) in substantially the form attached as ***Exhibit A,*** under the direction of the Principal Investigator identified in such Statement of Work, an employee of the University of Rochester.

The clinical research programs contemplated by this Agreement are of mutual interest and benefit to Rochester and Sponsor, and will further Rochester’s instructional and research objectives 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 hereby agree as follows:

1. RESEARCH; STATEMENT OF WORK.
	1. Rochester agrees to use its reasonable efforts to perform the clinical research project as described in each project specific protocol as may be amended from time to time and as approved by the Institutional Review Board (“IRB”), which is incorporated herein by this reference (“Protocol”) and (ii) the applicable SOW (the“**Research**”), which SOWs are incorporated herein; provided that neither party makes any representations or warranties regarding the completion of the Research or the achievement of any particular result or outcome. Each SOW will be in writing and signed by both parties. Unless otherwise agreed by the parties, each Statement of Work will include: (i) identification of the Protocol; (ii) the schedule or term for performance of the Research; (iii) the fees, reimbursable expenses and other compensation payable by Sponsor to Rochester for the Research; and (iv) a description of any Sponsor Background IP (defined below) provided to Rochester by Sponsor. Access to work carried out in Rochester’s laboratories in the course of the Research shall be entirely under the control of Rochester’s Key Personnel (as defined in the Statement of Work).
	2. In the event of any conflict between the terms and conditions of this Agreement and the Protocol, the terms and conditions of the Protocol shall control with respect to matters of the clinical conduct of the Research, and the terms of this Agreement shall control with respect to all other matters.
	3. Sponsor and Rochester shall comply with and conduct all aspects of the Research in compliance with all applicable federal, state, and local laws and regulations. Rochester shall obtain IRB approval for the Research and proof thereof shall be provided to Sponsor. Initiation of each Protocol and Rochester’s obligation to conduct the Research shall not begin until IRB approval is obtained. Prior to a subject’s participation in the Research, Rochester shall, to the extent required, obtain from each subject, a signed informed consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IRB and Sponsor, provided that the informed consent is consistent with Rochester’s policies, or a waiver of consent as directed by the IRB. Any proposed changes to the Protocol must be in writing and will not take effect until approved by the IRB. If such Protocol changes affect the contract terms (including the budget or payment terms), the Sponsor agrees to promptly work with Rochester to execute an amendment to this Agreement. Rochester shall promptly inform Sponsor of all adverse events or Research-related safety issues, as instructed in the Protocol or breaches of the Protocol of which Rochester becomes aware.
2. KEY PERSONNEL.
	1. Each SOW will identify the individuals named as “**Key Personnel**” for the performance of the Research at Rochester: (i) Principal Investigator; and (ii) co-Principal Investigator (if applicable).

The Key Personnel identified in the applicable SOW can be amended by written agreement between the parties to specify by name additional Rochester researchers, staff or graduate students.

* 1. Rochester will conduct the Research, on its campus, in accordance with the Statement of Work, under the direction of the Principal Investigator identified in the Statement of Work. Should a visit by the Principal Investigator to a Sponsor facility become necessary, Sponsor will coordinate and pay for Principal Investigator’s travel expenses.
	2. In the event that a Principal Investigator becomes unable or unwilling to continue the Research, Rochester will provide written notice to Sponsor and suggest a qualified researcher to replace such Principal Investigator. Sponsor may elect to (i) approve the replacement candidate suggested by Rochester; (ii) decline to approve such replacement candidate, in which case Rochester will provide the names of alternative qualified researchers as replacement candidates for the Principal Investigator until Sponsor approves a replacement candidate; or (iii) terminate the Research and this Agreement.
1. REIMBURSEMENT OF COSTS; PAYMENT TERMS.

As compensation for Rochester’s performance of the Research, Sponsor will pay Rochester the fees, reimbursable expenses and other compensation set forth in the applicable Statement of Work, subject to the limitations set forth in this Section. The amounts payable by Sponsor for Rochester’s performance of the Research will, in no event, exceed the amounts described in the research budget set forth in the applicable Statement of Work, unless Sponsor agrees to amend the applicable Statement of Work or approves in writing additional amounts (“**Research** **Budget**”). Rochester shall not be obligated to expend funds in excess of those provided in the Research Budget under the applicable SOW to conduct the Research. Unless otherwise specified in the applicable SOW, Rochester will issue invoices for amounts payable under this Section 4 no more frequently than on a monthly basis. Each invoice will be itemized as reasonably specified by Sponsor. Sponsor will pay Rochester all undisputed amounts thereunder within thirty (30) days after receipt of Rochester’s validly issued invoice. If any invoice is disputed, the disputed amount will be due and payable within thirty (30) days after resolution of such dispute. All amounts payable under this Agreement are denominated in United States dollars.

Sponsor shall make payments to Institution via ACH bank transfer using banking information provided at a later date and in accordance with the payment schedule set forth in Exhibit B and incorporated herein.

For purposes of identification, each payment shall include the title of the Research and the name of the Principal Investigators.

1. EQUIPMENT AND MATERIALS.
	1. Rochester Equipment and Materials. Rochester may not purchase any equipment, materials or other tangible items for the Research with funding provided by Sponsor or otherwise at Sponsor’s expense unless such equipment or items are set forth in the Research Budget. Unless otherwise expressly agreed in writing by the parties, title to any such equipment, materials or other tangible items purchased by Rochester for the Research shall vest in Rochester. If specified in the Research Budget, Sponsor shall reimburse Rochester for the actual out-of-pocket cost for such equipment, materials or other tangible items, without mark-up, overhead or other additional amounts.
	2. Sponsor Materials. During the Research, Sponsor may transfer materials for use in the Research as may be specified in an applicable Statement of Work to Rochester. Such materials together with all unmodified derivatives thereof shall be deemed “Sponsor Materials” for purposes of this Agreement. Sponsor shall retain all right, title and interest, including, but not limited to, intellectual property rights, in and to Sponsor Materials. Rochester shall use Sponsor Materials solely for the purpose of performing the Research. To the extent that Sponsor Materials include intellectual property used in Inventions (defined below), Sponsor grants to Rochester a perpetual royalty-free non-exclusive worldwide license to use the Sponsor Materials for non-commercial research and education purposes only. Rochester shall not sell or transfer Sponsor Materials to any other person or entity or use Sponsor Materials for any purpose other than the Research, without Sponsor’s prior written consent. Rochester shall comply with Sponsor’s written instructions provided to Rochester and applicable laws and regulations in the use of Sponsor Materials. Sponsor’s transfer of the Sponsor Materials to Rochester shall not constitute a sale thereof or a grant, option or license under any patent or other rights owned or controlled by Sponsor. Unless otherwise agreed to by Sponsor in writing, within thirty (30) days after the earlier of completion of the Research or termination of this Agreement or the applicable Statement of Work, Rochester shall destroy any Sponsor Materials in its possession or control.
2. INTELLECTUAL PROPERTY.
3. Inventorship of inventions conceived during the course of performing Research under this Agreement **(**“**Inventions**”) will be determined in accordance with U.S. Patent laws and ownership shall follow inventorship. Inventions invented solely by Rochester personnel shall be owned by Rochester (“**Rochester Inventions**”) and Inventions invented by both Rochester and Sponsor personnel (“**Joint Inventions**”) shall be owned by both Rochester and Sponsor. Rochester represents that all of its employees who may be involved in the Research have agreed to assign to Rochester all rights to Inventions, technology and software developed under this Agreement.
4. Patents - Rochester and Sponsor shall promptly provide in confidence a complete written disclosure to each other of any Invention first conceived or discovered in the performance of the work funded under this Agreement. In consideration of Sponsor’s sponsorship of the Research hereunder, Rochester shall grant to Sponsor a non-exclusive, non-transferrable, world-wide, royalty-free license to any Rochester Invention for internal research and development purposes and an option to acquire an exclusive license to the Rochester Invention. Rochester shall, at Sponsor's request and expense, pursue and obtain patent protection for Rochester Inventions in consultation with Sponsor. If Sponsor does not request patent protection at its expense, then Rochester shall notify Sponsor if it will seek to independently pursue patenting of such Rochester Invention, have the sole right to decide whether to pursue patenting of the Rochester Invention and, should it decide not to pursue patenting, the license granted herein shall be limited to the non-patented Invention. If Sponsor, after having requested patent protection for a Rochester Invention at its expense, decides at a later date that it no longer wishes to continue to pursue such patenting, then Rochester shall have the sole right to decide whether to continue to pursue patenting of the Rochester Invention, and the license granted herein shall thereafter be limited to the non-patented Rochester Invention. Within thirty (30) days of receipt of disclosure Sponsor will notify Rochester in writing whether or not it elects to secure a license to Rochester’s interest in the disclosed Rochester Invention (“**Election Period**”). Sponsor will then have ninety (90) days from the date of its notice of election to conclude such license agreement with Rochester (“**Negotiation Period**”). Said license will contain reasonable terms, will require diligent performance by Sponsor for the timely commercial development and commercialization of Rochester Inventions subject to the license, and will include Sponsor's obligation to reimburse Rochester for its patent costs for all Rochester Inventions subject to the license. If such license negotiation is not concluded within the Negotiation Period or if Sponsor does not notify Rochester of its wish to secure a license within the Election Period, neither Party will have any further obligation to the other with respect to Rochester’s interest in the Invention and the rights to such Invention will be disposed of in accordance with Rochester’s discretion. In all cases, Rochester reserves for itself a royalty-free, irrevocable license to make and use such Inventions for its own research and educational purposes. Such option shall also be extended to any Rochester interest in any Joint Invention for which the parties elect to pursue.

If Sponsor requests patent protection at its expense, in addition to the license granted in the prior paragraph, Sponsor shall be entitled to a one hundred eighty (180) day period from the date that Rochester files for patent protection for the Rochester Invention to negotiate the terms of an exclusive license agreement and Rochester and Sponsor agree to negotiate these license terms in good faith. Such option shall also be extended to Rochester’s rights to any Joint Invention for which the parties elect to pursue patenting.

Rochester shall, at Sponsor’s request and expense, pursue and obtain patent protection for Joint Inventions in consultation with Sponsor. Rochester shall keep Sponsor reasonably informed regarding the status of any patent application filed with respect to a Joint Invention and will give Sponsor reasonable opportunity to review and comment.

1. Technology Other than Patented Technology – “**Data**” means all data, results and information generated by Rochester in performance of the Research. All Data arising from the Research shall owned by Rochester. Rochester hereby grants Sponsor a non-exclusive, royalty free, worldwide license, to use all such Data in accordance with the scope of the informed consent and HIPAA authorization given by the Research subject. All rights in technology (such as tangible materials, works of authorship, software) created in the performance of the Research by personnel of Rochester shall be owned by Rochester. In consideration of Sponsor’s sponsorship of the Research hereunder, Rochester shall grant to Sponsor a non-exclusive, non-transferrable, world-wide, royalty-free license to any such technology so long as Sponsor notifies Rochester of its desire for such license within thirty (30) days after the complete written disclosure is provided by Rochester to Sponsor. Upon receipt of a written description or sample of such technology, Sponsor shall have a one hundred eighty (180) day period to negotiate the terms of an exclusive license agreement and Rochester agrees to negotiate these license terms in good faith. During this period, Rochester will not offer a commercial license to any other party.
2. License Terms - Any license granted shall be subject to Rochester's intellectual property policies and Rochester's agreement with other sponsors of research and providers of research materials. Such license shall provide:

1. for Sponsor (and its sublicensees, if any) to exert diligent efforts to introduce products and services utilizing the licensed technology into public use as rapidly as practicable;
2. for a royalty that is usual and customary in the trade;
3. for termination in the event Sponsor has not introduced licensed products or services into public use, or is not actively seeking to due so, within a time period acceptable to Rochester;
4. for indemnity terms acceptable to Rochester;
5. for Rochester to retain a nonexclusive license, with the right to grant licenses to non-profit and academic institutions, for non-commercial research purposes only;

6. that the license shall be subject, when research is funded by the United States government to rights retained by the government in accordance with P.L. 96-517, as amended by P.L. 98-620, and when such funding is NIH funding, Rochester's obligations regarding the NIH Guidelines for Obtaining and Disseminating Biomedical Research Resources, including, but not limited to, the obligation to ensure that research tools will be available to academic research community on reasonable terms.

7. PUBLICATION.

Prior to the publication of abstracts, manuscripts, presentations or other communications describing the Research, Rochester will submit the publication materials for review by Sponsor at least sixty (60) days prior to submission for publication; provided that, if such publication materials are for a presentation, Rochester will submit the presentation materials for review by Sponsor at least thirty (30) days prior to submission for publication. If the publication discloses any patentable subject matter, the publication submission may be delayed up to an additional sixty (60) upon the request of Sponsor, but only if and to the extent reasonably required to protect any patent rights being claimed by either party in such subject matter (e.g., by the preparation and filing of an appropriate patent application). Further, if Sponsor identifies any Confidential Information during its review, then prior to the submission of any materials for publication Sponsor may give written notification to Rochester of Sponsor’s identification of Confidential Information. Upon receipt of such written notice from Sponsor, Rochester will expunge all Confidential Information identified by Sponsor from the proposed publication materials prior to submission for publication and will not disclose or publish any such Confidential Information. Such Sponsor required modification will not result in withholding any study results from academic publication. Upon Sponsor’s request, Rochester will (a) remove all references to Sponsor or Sponsor’s support or other role in the research (when not otherwise required by the guidelines of an academic organization), or (b) provide, in accordance with customary standards, an appropriate acknowledgement of Sponsor’s support or other role in the research in any such publication or presentation about the research.

8. CONFIDENTIALITY.

* 1. For purposes of this Agreement, “Confidential Information” means all information disclosed or submitted by one party (the “**Disclosing Party**”) to the other party (the “**Receiving Party**”) which (i) is designated in writing as confidential information at the time of disclosure or (ii) should reasonably be considered confidential given the nature of the information or the circumstances of disclosure. All Sponsor Inventions, Sponsor Technology, Sponsor background intellectual property or technology or other Sponsor provided specifications, directions, materials, schematics, formulae or other information will be Sponsor Confidential Information. Confidential Information does not include information which: (i) was known to the Receiving Party without restriction prior to the disclosure hereunder; (ii) was received by the Receiving Party from a third party rightfully in possession of such information; (iii) is in the public domain at the time of disclosure hereunder or subsequently entered the public domain without the fault of the Receiving Party or without any breach of this Agreement; (iv) is independently known to the Receiving Party prior to its receipt thereof or is discovered independently by an employee or student of Rochester who had no access to or knowledge of the information supplied by the Sponsor under this Agreement; (v) or is required to be disclosed by law, provided that the Receiving Party (a) promptly notifies the Disclosing Party prior to disclosing any Confidential Information so as to provide the Disclosing Party with sufficient time to oppose or seek to limit such disclosure, and (b) if the Disclosing Party’s efforts to oppose or limit such disclosure are ultimately unsuccessful, discloses Confidential Information only the extent required to comply with applicable law and uses commercially reasonable efforts to obtain confidential treatment of any Confidential Information disclosed.
	2. Each party agrees that it will not disclose or use any Confidential Information for any purpose outside the scope of this Agreement, except with the other party’s written permission. Confidential Information may be disclosed by the Receiving Party to its own employees or professional staff or that require access to such Confidential Information for purposes of performing under this Agreement, including any SOW.
	3. Each party retains the right to refuse to accept any Confidential Information of the other party which is not considered to be essential to the completion of the Research or the performance of any obligations under this Agreement or any SOW. The obligations of confidentiality under this paragraph shall survive and continue for five (5) years after the termination of this Agreement.
1. REPORTS; RECORD RETENTION.

Rochester shall furnish Sponsor letter reports during the term of Statement of Work summarizing the Research conducted no less frequently than annually Such reports will include a description of the progress and activities of the Research during the reporting period and in accordance with the milestone schedule set forth in the applicable Statement of Work.A final report setting forth the accomplishments and significant Research findings shall be prepared by Rochester and submitted to the Sponsor within ninety (90) days of the completion of the Research. During the term of this Agreement, representatives of Rochester will meet with representatives of Sponsor upon Sponsor’s request at times and places mutually agreed upon to discuss the progress of the Research. Institution shall retain Research records for such time as required by applicable law.

1. TERM; TERMINATION.
	1. Term. The term of this Agreement will commence on the Effective Date and will continue until terminated in accordance with this Section 10 (“**Term**”). Each SOW entered into during the Term will continue in full force and effect until completed, and the Term of this Agreement will extend to at least the end date of any outstanding SOW.
	2. Termination. This Agreement or any SOW may be terminated by Sponsor at any time upon the receipt of sixty (60) days written notice to Rochester. In addition, Rochester may terminate this Agreement or any SOW at any time on sixty (60) days’ written notice to Sponsor, or if Sponsor is in breach of this Agreement, including for the failure to make any payment required hereunder (and that is not subject to a good faith dispute), this Agreement or such SOW shall terminate on the thirtieth (30th) day after Sponsor receives written notice of breach, unless payment is received before such thirtieth (30th) day.
	3. Effect of Termination. Upon any termination of the Term or the Research, Rochester shall promptly conclude the Research. All costs associated with early termination of the Term or Research shall be allowable to the extent that such costs are non-cancellable or unavoidable, and were entered into in accordance with the Research Budget prior to Rochester’s receipt of the termination notice from Sponsor. Sponsor will reimburse Rochester for all expenses incurred prior to the termination date in accordance with the applicable Research Budget which have not been reimbursed to Rochester by Sponsor. In the event of termination, Rochester shall submit to Sponsor a final financial report in accordance with Paragraph 4 of this Agreement and a final report regarding the Research in accordance with Paragraph 9 of this Agreement. Termination or expiration of this Agreement will not affect either party’s rights and duties under Paragraphs 4, 6, 7, 8, 9, 10(C), 11, 12, 13, 14, 15 and 18 through 25 hereof.
2. NOTICES.

Any notices given under this Agreement shall be in writing and delivered by
certified or registered return receipt mail, postage prepaid, or by facsimile addressed to the parties as follows:

|  |  |
| --- | --- |
| For Sponsor: | For Rochester:Associate VP for Research AdministrationOffice of Research and Project Administration 518 Hylan BuildingRC Box 270140 Rochester, New York 14627 Email: abeckman@orpa.rochester.edu(585) 275-4031 (Telephone)(585) 275-9492 (Facsimile) |

1. PUBLICITY.

 Neither party shall use the name, tradenames or trademarks of the other party or the other party’s employees in connection with any products, promotion, advertising, or, with respect to Rochester, in any abstracts, manuscripts, presentations or other communications describing any research without the prior written permission of an authorized representative of the other party. The foregoing shall not, however, preclude any legally required disclosure or acknowledgement of sponsorship as required by the guidelines of an academic organization.

1. WARRANTIES.

Rochester warrants that it has the right, power and authority to enter into this Agreement. ROCHESTER MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, THE CONDITION OF THE RESEARCH OR ANY INVENTIONS) OR PRODUCT(S), WHETHER TANGIBLE OR INTANGIBLE, CONCEIVED, DISCOVERED OR DEVELOPED UNDER THIS AGREEMENT; OR THE NON-INFRINGEMENT, OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE RESEARCH OR ANY SUCH INVENTION OR PRODUCT.

1. USE OF RESEARCH RESULTS AND LIABILITY.

Sponsor agrees to hold harmless, indemnify and defend Rochester from all claims, suits, actions, proceedings, demands, liabilities, demands, damages, expenses and losses arising out of (i) the conduct of the Research, or (ii) use, sale or other disposition by the Sponsor, or by any party acting on behalf of or under authorization from the Sponsor of the use of the Research results or of products made by use of the results of the Research performed hereunder. The provisions of this paragraph shall survive termination, provided that Rochester provides to Sponsor (i) prompt written notice of any such claim, (ii) sole control over the defense and settlement of such claim and (iii) reasonable cooperation (at Sponsor’s expense) in connection with Sponsor’s development and settlement thereof.

Except for breaches of Section 8, neither party shall be liable to the other party for any direct, consequential, or other damages suffered by any licensee or any others resulting from the use of the Research or any Invention. The provisions of this paragraph shall survive termination of this Agreement.

1. SUBJECT INJURY.

 If a Research subject suffers an adverse reaction, medical illness, or injury which was directly caused by any properly performed procedures required by the Protocol, Sponsor shall reimburse for the reasonable and necessary expenses of diagnosis and treatment of any Research subject injury, including hospitalization, but only to the extent such adverse reaction, medical illness or injury are not directly caused by (i) Rochester’s negligence or willful misconduct; (ii) the natural progression of an underlying or pre-existing condition or events, unless exacerbated by participating in the Research; or (iii) Rochester’s failure to adhere to and comply with the specifications of the Protocol, provided that deviations from the Protocol and written instructions resulting from an imminent threat to the health or safety of a Research subject that do not cause the injury to the Research subject will not disqualify Institution from reimbursement under this provision.

1. THIRD PARTIES.

Upon advance written notice to Institution, Sponsor may utilize any third party it deems appropriate to facilitate the conduct of the work under this Agreement or any study activity in the Protocol; provided, however, that (i) Sponsor shall require said third parties to comply with all applicable terms and conditions of this Agreement and applicable portions of the Protocol and Informed Consent, (ii) Sponsor shall require any third party that has access to protected health information (PHI) or personally identifiable information (PII) of study subjects to safeguard such information and report any loss or unauthorized access of such information to Institution, (iii) Sponsor shall report to Institution any loss or unauthorized access of such information, and (iv) Sponsor shall be liable to Institution for any loss or damage incurred by Institution arising out of the acts or omissions of said third parties.

1. INSURANCE.

Sponsor will procure and maintain during the term of this Agreement comprehensive liability and, prior to any commercial exploitation of any product or service rising out of the Research, product liability insurance to the full amount of Sponsor insurance limits, but in no event less than $3,000,000 in the aggregate, with a reputable and financially secure insurance carrier or through self-insurance. If through a carrier, the insurance will include Rochester, its trustees, directors, employees, agents and students as additional insureds with respect to this Agreement. If through a carrier, this insurance will be written to cover claims incurred, discovered, or made during or after the expiration of this Agreement.

1. COMPLIANCE.

(A) COMPLIANCE WITH FRAUD AND ABUSE LAWS. Sponsor represents and warrants that neither it, nor any of its officers, directors, shareholders holding a fifty percent or greater equity interest in Sponsor, employees and agents: (i) have been excluded from participation in any of the government health care programs, (ii) have been indicted for, convicted of or pled guilty or nolo contendere to any felony or misdemeanor related to the practice of a health care profession, the fraud and abuse laws or controlled substances laws, (iii) have had a civil monetary penalty assessed against them (including monies paid through a settlement process) for presenting a false or fraudulent claim to any government health care programs, or (iv) are now or have ever been under investigation by any government agency for conduct which might result in any of the above.

(B) COMPLIANCE WITH HIPAA. Sponsor acknowledges that Rochester is a “Covered Entity” within the meaning of the Health Insurance Portability and Assurance Act (“HIPAA”) and that information may be exchanged under the terms of this Agreement that would constitute “protected health information” (“PHI”) as that term is used in HIPAA. Therefore, in connection with PHI, Sponsor agrees that (i) it may not use or disclose such information other than in connection with this Agreement; and (ii) it may not disclose such information in a manner that would violate the proposed regulations under HIPAA if such disclosure were done by Rochester. Sponsor agrees to adopt appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement and to report to Rochester any use or disclosure of PHI in violation of this Agreement of which it becomes aware as soon as reasonably practicable. Sponsor agrees that that if any portion of its obligations under this Agreement are performed through a subcontractor or agent that the subcontractor or agent must agree to the same restrictions and conditions that apply to the Sponsor with respect to PHI. Sponsor must make PHI available pursuant to section 164.514(a) (“Right of access for inspection or copying”) of the proposed privacy regulations pursuant to HIPAA. In connection with this obligation, Sponsor agrees to make its internal practices, books and records relating to the use and disclosure of PHI available to Health and Human Services Administration for the purpose of determining compliance with the privacy regulations. Sponsor agrees that upon termination of this Agreement, Sponsor will return or destroy all PHI received from Rochester and will not retain copies of such information.

1. FORCE MAJEURE.

Except for payment obligations hereunder, neither party shall be liable for any failure to perform as required by this Agreement to the extent such failure to perform is caused by any reason beyond a party’s reasonable control, such as changes in law or regulation, floods, earthquakes, acts of God, pandemic, explosion, war, terrorism, or other natural disasters.

1. ASSIGNMENT.

 Neither party shall assign its rights or duties under this Agreement to another without the prior express written consent of the other party; provided, however, that Sponsor may assign this Agreement to a successor in ownership of all or substantially all its business or assets to which this Agreement relates. Such successor shall expressly assume in writing the obligation to perform in accordance with the terms and conditions of this Agreement. Any other purported assignment shall be void.

1. SEVERABILITY.

 In the event a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, and they shall continue in full force and effect.

1. INDEPENDENT CONTRACTOR.

 Each party shall be deemed to be an independent contractor of the other party, and neither shall be considered an agent, employee, joint venture or partner of the other. Neither party shall have authority to make warranties or representations or enter agreements on behalf of the other, nor shall either party be bound by the acts, statements or conduct of the other.

1. INDEPENDENT INQUIRY.

Nothing in this Agreement shall be construed to limit the freedom of researchers who are participants in this Agreement, whether paid under this Agreement, or not, from engaging in similar research inquiries made independently under other grants, contracts or agreements with parties other than the Sponsor.

1. HEADINGS.

The paragraph headings herein are for convenience only and shall not affect the construction or interpretation of this Agreement.

1. ENTIRE AGREEMENT CHANGES.

This Agreement and its exhibits contain the entire agreement between the parties, and supersede any prior or contemporaneous representations or agreements, written or oral regarding the subject matter thereof. No amendments or changes to this Agreement shall be effective unless made in writing and signed by authorized representatives of Rochester and Sponsor. All correspondence regarding terms of this Agreement shall be sent as specified in Paragraph 11.

1. GOVERNING LAW.

 This Agreement shall be governed by the laws of the State of New York as adjudicated by a court of competent jurisdiction.

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

|  |  |
| --- | --- |
| SPONSORBy: Name: Title: Date:  | University of RochesterBy: Name: Title: Date:  |

EXHIBIT A

STATEMENT OF WORK

This Statement of Work is entered into by and between the University of Rochester and SPONSOR, pursuant to the Master Sponsored Research Agreement dated \_\_\_\_\_\_\_\_\_\_\_\_and hereby incorporates the terms of such Master Research Agreement;

Protocol:

Scope of Work Date:

Title:

Period of Performance:

Rochester Principal Investigator:

Detail Scope of Work:

Total Budget:

**Payment:**

[***Option 1***: All payments under this Statement of Work will be invoiced and paid pursuant to Section 4 of the Master Agreement.]

[***Option 2***: This is a fixed funding agreement; the total identified below will not to be exceeded without prior written consent from Sponsor. Upon execution of this Agreement, Rochester will submit invoices for payment due within thirty (30) days from receipt of the invoice in accordance with the following schedule:

 $\_\_\_\_\_\_\_ due upon execution of this Agreement

 $\_\_\_\_\_\_ due monthly for \_\_\_ months

 $\_\_\_\_\_\_ due upon receipt of the final report

 Total: $\_\_\_\_\_\_\_ (including overhead)]

Background IP:

*Signatures to begin on following page*

IN WITNESS WHEREOF, This Scope of Work implementing the Master Research Agreement dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has been signed by the Parties as of the Scope of Work date first above written.

|  |  |
| --- | --- |
| [\_\_\_\_\_\_\_\_\_\_]By: Name: \_\_\_\_Title: \_\_\_\_Date:  | University of RochesterBy: Name: Title: 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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_