# CLINICAL TRIAL AGREEMENT

This **Clinical Trial Agreement** (“**Agreement**”) is entered into as of the date of last signature hereto (the “**Effective Date**”) by and between:

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| --- | --- |
| **Parties:** | [**Institution’s Legal Entity Name**], with offices at [Institution’s full address] (the “**Institution**”) and, |
| [**Sponsor’s Legal Entity Name**]**,** a [state of incorporation] corporation with offices at [sponsor’s full address] (together with its Affiliates (as defined below), the “**Sponsor**”) |

Hereafter, Sponsor and Institution are sometimes referred to individually as “**Party**” or collectively as the “**Parties**.”

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| **Study & Protocol:** | In connection with a clinical trial (the “**Study**”) conducted pursuant to Protocol [Protocol Number], “[Protocol Title]” (the “**Protocol**”). |
| **Investigator:** | The Study will be conducted under the immediate supervision of [**Investigator full name**] (the “**Investigator**”). |
| **Study Drug and/or Study Device:** | [Name of Sponsor’s Study Drug(s) and/or Device(s)] provided for the Study. |
| **CRO:** | [Name of entity providing contract research services to Sponsor]. |

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| **Notice:** | If to Institution:[Institution’s legal contact information]Attention: Email:  |
| If to Sponsor:[Sponsor’s legal contact information]Attention: Email:  |

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| --- |
| The language of the agreement that follows, not inclusive of any attachments or exhibits, is modified from the originally provided template: [x]  Yes [ ]  No. |

The Parties agree as follows:

Scope of The Agreement

Compensation. Sponsor will pay the Institution’s payee as set forth in the Budget and Payment Schedule attached hereto as **Exhibit A** and incorporated herein by reference. The amounts payable by Sponsor under this Agreement represent the fair market value of the services associated with the Study and have not been determined in a manner that takes into account the volume or value of any referrals or business. The Investigator and all other personnel, employees, contractors and agents of Institution who are involved in the Study (“**Study Personnel**”) will be compensated by the Institution for work done on the Study, and will not be directly compensated by Sponsor for such work. Institution shall submit a complete and accurate IRS Form W-9 to Sponsor before any payment is made hereunder. The Parties agree that the payment will be made to Institution’s payee as designated on the IRS Form W-9.

Study Conduct. Institution will conduct the Study at the locations listed on the FDA 1572 (“Study Site(s)”) in compliance with (i) the Protocol; (ii) the obligations of Institution under this Agreement; (iii) all applicable laws and regulations; (iv) good clinical practice requirements as may be published by the FDA from time to time; and (v) the applicable established requirements of regulatory authorities.

Compliance. Institution represents that Investigator is an employee or contracted investigator of Institution and has executed the signature page of the Protocol, and shall require that the Investigator and Study Personnel will comply with all terms of the Protocol and this Agreement. An “Affiliate” is any business entity which controls, is controlled by, or is under the common control with the Party. A business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity

IRB Approvals and Informed Consent Form. Prior to the commencement of the Study at the Institution, Institution will obtain approval for the Study, including approval of the Protocol, the informed consent form and, if applicable, pediatric assent form (collectively, “**ICF**”), and any amendments to any of the foregoing, from the applicable Institutional Review Board (“**IRB**”) in accordance with applicable laws and regulations. Institution or Investigator will promptly supply Sponsor with (i) appropriate evidence of IRB approval, and (ii) a copy of the IRB-approved ICF, and (iii) any amendments to the ICF later approved by the IRB prior to use of such amended ICF by Institution.

Study and Results Registration. Prior to enrollment of the first subject in the Study, Sponsor agrees, as applicable, to ensure that the Study is fully registered on www.clinicaltrials.gov in accordance with Public Law 110-85. Sponsor agrees to update the information on www.clinicaltrials.gov as necessary and report the results of this Study in compliance with applicable laws

Human Research Protection. Sponsor will use reasonable efforts to promptly report to Investigator any findings discovered during Sponsor’s site monitoring process that could reasonably affect the safety of participants or their willingness to continue their participation in the Study. Sponsor agrees to, in a timely manner, notify the Investigator and Institution of any findings of the data safety monitoring board, if applicable, or data analysis from the Study: (a) materially and adversely affect the health or safety for past or current Study subjects; (b) reasonably affect the willingness of Study subjects to continue participation in the Study; (c) reasonably influence the conduct of the Study or (d) alter the IRB’s approval to continue the Study. In each case, the Investigator shall be responsible for notifying its IRB to determine whether and how the reported information, or part of it, should be provided to Study subjects. Institution agrees to provide Sponsor a copy of or the details of its communication to Study subjects pursuant to this section.

Study Drug.

Institution and Investigator acknowledge that the Study Drug provided for this Study and all related intellectual property is owned and/or controlled by Sponsor and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Institution, Study Personnel or Investigator for the Study, shall be construed to grant to either Institution, Study Personnel or Investigator any rights in or to the Study Drug and/or Study Device.

Sponsor will provide the Study Drug and any control/placebo materials administered to Study subjects as part of the Study free of charge to Institution for administering or dispensing solely by or under the supervision of Investigator to Study subjects at the Study Site in compliance with the Protocol.

Confidentiality

Sponsor Confidential Information. Institution will (and will cause Investigator and Study Personnel to) keep confidential and not disclose any information provided by or on behalf of Sponsor or that is generated, discovered, or obtained by any Party as a result of the Study (other than patient medical records), including the Study results, Study Inventions and information related thereto (“**Confidential Information**”). Sponsor shall endeavor to mark tangible Confidential Information provided to Institution as “Confidential” and to confirm verbally disclosed Confidential Information as confidential in writing within a reasonable period of time, given the understanding that failure to do so does not constitute a designation of non-confidentiality, when the confidential nature is apparent from context and subject matter. Except as provided for in this Agreement, Institution and Investigator will use, and will cause Study Personnel to use, Confidential Information only for purposes of the Study and for no other purpose. The obligations of this section will survive expiration or termination of this Agreement for a period of five (5) years after the termination or expiration of this Agreement. Confidential Information will not include information that:

### is or becomes publicly available through no fault of Investigator, Study Personnel or Institution;

### was known to Investigator or Institution without obligation of confidentiality prior to receiving it either directly or indirectly from Sponsor under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institution from Sponsor;

### is disclosed to Investigator or Institution by a third party, as demonstrated by written records, without violation of law or any obligation of confidentiality; or

### can be shown by written records of Institution or Investigator to have been independently developed by Institution or Investigator without reference to or reliance upon any Confidential Information.

Permitted Disclosure. Notwithstanding any other provision of this Agreement, Institution and Investigator may disclose Confidential Information only to the extent required:

### to comply with an applicable governmental law, rule, regulation or order, after prompt notice to Sponsor and provided that Investigator and Institution reasonably cooperate with Sponsor’s efforts to limit such disclosure by appropriate legal means;

### to protect any Study subject’s safety or provide appropriate medical care for any Study subject, or to prevent a public health emergency with prompt notice to Sponsor;

### to provide Confidential Information to others who have a need to know in connection with the Study, provided that the Institution ensures that each such individual is bound by an obligation of confidentiality at least as stringent as those set forth herein; or

### for purposes of insurance or reimbursement by a third party payer for medical treatment of a Study subject related to the procedures included in the Protocol.

Institution Confidential Information. During the performance of the Study by Institution under this Agreement, Sponsor and/or its representatives may be provided or otherwise gain access to information relating to Institution’s business or research operations, policies or procedures or financial information (“**Institution Confidential Information**”). Neither Sponsor nor its representatives may use and disclose Institution Confidential Information without Institution’s prior written permission; except however, Sponsor and/or its representatives may use and disclose Institution Confidential Information in order to conduct and monitor the Study or to the extent such disclosures are required by Applicable Laws, including as may be required by the FDA in connection with any filings. Sponsor and/or its representatives will use reasonable care to safeguard the security and confidentiality of Institution Confidential Information

Ownership and Use of Study Data, Biological Materials, and Other Materials

Ownership and Use. Sponsor owns all Study lab test results, case report forms (“**CRF**”) and other reports completed or information generated by Institution or Investigator required under the Protocol, Agreement or other written instruction by Sponsor (collectively “**Study Data**”), excluding Institution’s patient medical records and Investigator’s personal notes. Sponsor hereby grants to the Institution a non-exclusive, non-transferable, non-sublicensable right to use the Study Data solely for its own internal, non-commercial research, quality assurance, and educational purposes.

Biological Materials. Sponsor will collect, use, store, and disclose any blood, serum, urine, saliva, bone marrow or tissue sample/specimen and any tangible material isolated therefrom, including but not limited to any DNA, RNA and other biological substances (“**Biological Sample**”) it receives only in accordance with the uses set forth in the Protocol and ICF and in compliance with applicable law, and in any event will not collect, use, store, or disclose any individually identifiable health information attached to or contained within the Biological Sample in any manner that would violate any obligation under this Agreement. Biological Samples, diagnostic tests, or other materials collected for a Study will be used by Institution and Investigator solely for purposes of such Study and only in accordance with the ICF and as specified in a Protocol and this Agreement. Sponsor shall not use Biological Samples for future research unless provided for in the applicable Study Protocol and ICF.

Identifiable Health Information. Sponsor agrees to use, store, and disclose individually identifiable health information collected or produced by Institution or Investigator in accordance with the Protocol only for the purpose of complying with applicable law, provided that all such uses are disclosed in the IRB-approved ICF. Sponsor may use information that is not identifiable under any applicable U.S. laws for any research and development purpose. Sponsor will not contact any Study subjects, unless permitted by the ICF. Sponsor will not use or share individually identifiable health information for any mailing list or for any marketing purpose. The Parties agree that all protections, ownership rights and use restrictions afforded by this Agreement to the health information and data of Study subjects will apply equally to any health information or other data collected from such Study subjects’ pregnant partners, if any and regardless of when during the applicable Study the partner becomes pregnant, whether or not a pregnant partner is formally recognized by the IRB as being a human research subject enrolled in the Study.

Informed Consent and Protected Health Information.

Informed Consent. Institution shall ensure that Investigator will obtain from each individual (or such individual’s legal representative) who is to be screened for participation in the Study, a properly executed ICF, as reviewed by Sponsor and approved by the IRB before such individual is allowed to be screened for participation in the Study.

Protected Health Information. Institution shall comply with all relevant and applicable laws and regulations governing the privacy and security of health information. To the extent required by applicable law, Institution will also require Investigator, all Study Personnel and any other third parties involved in the conduct of the Study to comply with applicable law. Institution shall treat confidentially all information regarding diagnosis, history or treatment that allows unique identification of an individual (“**Protected Health Information**”), as that term is defined by 45 CFR §164.501, as amended. To the extent required by applicable law, Institution and Sponsor will implement and maintain such privacy and security safeguards as are necessary to ensure that Protected Health Information is adequately protected from unauthorized access, and that any disclosure of such information is compliant with applicable HIPAA requirements. Institution and Principal Investigator shall ensure that all consents and authorizations required by applicable law are obtained from Study subjects, such that Sponsor and each of Sponsor's contractors are permitted to access the Protected Health Information of any Study subject for the purpose of fulfilling any obligation under this Agreement, or for the purpose of complying with any requirement under applicable law or any other legal or regulatory requirement to which Sponsor is subject.

Debarment

Institution represents and certifies that it will not, in the course of performing the Study, use in any capacity the services of any person or entity who has been debarred, disqualified as an investigator, or restricted by the FDA pursuant to the Generic Drug Enforcement Act of 1992 or any other equivalent or successor statutes, rules or regulations. Institution represents that none of the Institution, Investigator or the Study Personnel has been, nor is presently, excluded from participation in any government healthcare program, convicted of any materially relevant offense, or otherwise deemed ineligible for participation in healthcare programs, nor is aware of any pending or potential actions that would give rise to any such ineligibility or is the subject of a disqualification proceeding or has not been disqualified as a clinical investigation participant pursuant to any authority rules. Institution will immediately notify Sponsor in writing if during the course of the Study, any of Institution, the Study Personnel or Investigator: (i) is debarred, disqualified or receives notification of any investigation by his/her professional governing body, any regulatory authority, including the FDA, or other government authority or (ii) receives notification of any restriction on his/ her clinical privileges at Institution and/or Study Site.

Records Maintenance and Retention.

Investigator and shall cause Institution will maintain adequate and accurate records relating to the disposition of the Study Drug and/or Study Device and the performance of all required Protocol procedures on Study subjects, including but not limited to, original documents, data, and records related to the Study (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, evaluation checklists, pharmacy dispensing records, recorded data regardless of medium, x-rays, subject files, and records wherever so held) (collectively “**Source Documents**”) medical records, charts pertaining to individual Study subjects, CRFs, accounting records, notes, reports, and data. Institution will retain these documents for the time required by applicable law and regulation. Sponsor shall provide written notice to Institution to notify of the events stated in 21 CFR 312.62(c) so that Institution may comply with its document retention obligations stated herein. Institution will notify Sponsor in writing prior to destruction of any Study-related records and, if requested by Sponsor, shall continue to retain the documents, with reasonable additional fee to be paid by Sponsor.

Monitoring and Auditing.

Sponsor Monitoring. At reasonable times and upon reasonable notice, Sponsor and its respective appointed representatives shall have the right to inspect, audit, and monitor the Study Site, Institution’s facilities, and all Study Data and associated Source Documents. Each of the Institution and Investigator will cooperate with Sponsor and its appointed representatives with respect to such inspections, audits and monitoring visits. Sponsor's and its representatives' access to Institution facilities and Study-related records will survive termination or expiration of this Agreement for the later of: (i) two (2) years following completion or termination of the Study; or (ii) as otherwise reasonably necessary to support regulatory and/or marketing approval of the Study Drug/Study Device.

Regulatory Inspections. Institution and Investigator will notify Sponsor immediately upon receiving notice of, and will reasonably cooperate with Sponsor on, any impending inspection or other action related to the Study by the FDA or other governmental or regulatory authority. If not legally prohibited, Institution will allow Sponsor’s representatives to attend any such inspection and promptly provide Sponsor with a copy of any documentation relating to the Study received from or sent to the FDA or any other regulatory authority.

Regulatory Correspondence. Institution and Investigator shall send Sponsor a copy of all correspondence with the IRB and FDA, including any correspondence relating to continuing review. Institution and the Investigator shall promptly notify Sponsor in writing of any communication from IRB and any national or state authority.

Inventions

**[standard version]**

All inventions, methods, works of authorship (excluding publications created in accordance with the publication provisions of this Agreement), know-how or discoveries that are made, conceived, or reduced to practice by Institution, Investigator or Study Personnel as a result of or in connection with the conduct of the Study; (i) that incorporate or use Confidential Information; or (ii) that are directly related to the Study Drug and/or Study Device, and in each case together with all intellectual property rights relating thereto (collectively, “**Study Inventions**”), will be the sole and exclusive property of Sponsor or its designee. Institution and Investigator will, and will cause all Study Personnel to, promptly disclose all Study Inventions to Sponsor in writing. Institution hereby assigns, and will cause Investigator and Study Personnel to assign, all right, title and interest in all Study Inventions to Sponsor or its designee. At Sponsor’s request and expense, Institution shall take, and shall cause Investigator and Study Personnel to take, all additional actions as Sponsor deems reasonably necessary to perfect the interest of Sponsor or its designee in Study Inventions or to obtain patents or otherwise protect the interest of Sponsor or its designee in Study Inventions.

It is recognized and understood that the inventions and technologies of Institution existing prior to the Effective Date are Institution’s separate property and are not affected by this Agreement. Ownership of all other inventions that are not Study Inventions shall be determined in accordance with U.S. inventorship law.

**[joint invention version]**

Study Inventions. Institution will promptly disclose, and will cause Investigator and Study Personnel to disclose, to Sponsor in writing all inventions, improvements or discoveries that are conceived or reduced to practice by Institution, Investigator or Study Personnel, whether solely or jointly, as a result of or in connection with the conduct of the Study (each an “**Invention**”). All inventions, improvements or discoveries that are conceived or reduced to practice by Institution, Investigator or Study Personnel (i) that incorporate or use Confidential Information, or (ii) that are directly related to the Study Drug and/or Study Device and together with all intellectual property rights relating thereto (collectively, “**Study Inventions**”), will be the sole and exclusive property of Sponsor or its designee. Institution hereby assigns all right, title and interest in all Study Inventions to Sponsor or Sponsor's designee. At Sponsor’s request and expense, Institution shall take, and shall cause Investigator and Study Personnel to take, all additional actions as Sponsor deems reasonably necessary to perfect the interest of Sponsor or its designee in Study Inventions or to obtain patents or otherwise protect the interest of Sponsor or its designee in Study Inventions.

Other Inventions. Institution shall own all right, title and interest in and to all Inventions (other than Study Inventions) that are made solely by Institution, Investigator or Study Personnel, and in each case together with all intellectual property rights relating thereto (“**Institution Inventions**”). Sponsor and Institution shall jointly own all Inventions other than Sponsor Inventions and Institution Inventions that are jointly made by Institution, Investigator, or Study Personnel and one or more employees, agents, independent contractors or related personnel of Sponsor, and in each case together with all intellectual property rights relating thereto (“**Joint Inventions**”). Subject to the option rights granted to Sponsor in this section, each Party shall have the right to freely exploit and grant licenses under all Joint Inventions without the consent of, or a duty of accounting to, the other Party.

License to Other Inventions. Institution hereby grants to Sponsor the first option to negotiate for an exclusive (or, at Sponsor’s election, non-exclusive), worldwide, royalty-bearing license, with the right to sublicense, under Institution’s interest in any and all Institution Inventions and Joint Inventions for all purposes on reasonable and customary terms and conditions (the “**Option**”). Sponsor shall advise Institution in writing within ninety (90) days after Institution’s disclosure to Sponsor of a particular Institution Invention or Joint Invention (such 90-day period, the “**Option Period**”) whether it wishes to exercise its Option with respect to such Invention. If Sponsor exercises its Option with respect to a particular Institution Invention or Joint Invention, the Parties shall in good faith negotiate the terms of a license agreement, for a period of up to six (6) months from the date on which the Option is exercised, or such longer period as may be determined by the mutual consent of Sponsor and Institution (such period, the “**Option Negotiation Period**”). Institution agrees that it shall not disclose any Institution Invention or Joint Invention to a third party until such time as the Option for the applicable Institution Invention or Joint Invention has expired without being exercised by Sponsor or, if Sponsor exercised such Option, the Option Negotiation Period has expired. Notwithstanding the foregoing, Institution shall be permitted to disclose any Institution Invention or Joint Invention at any time to the extent necessary to seek patent protection for such invention, or in accordance with Section 4. If Sponsor and Institution fail to enter into a license agreement with regard to a specific Institution Invention or Joint Invention within the applicable Option Negotiation Period or during such extension of time as the Parties may mutually agree, Institution may commercialize such invention and/or grant to a third party license rights under its interest in such invention.

Publication

Investigator will submit all proposed publications or presentations along with the name of the intended scientific journal, forum or conference, to Sponsor sixty (60) days prior to submission of the publication or presentation. Institution and Investigator will delete references to Sponsor’s Confidential Information (other than Study Data and information necessary for the complete and accurate presentation of the Study results) in any paper or presentation and, at Sponsor’s request, delay such publication or presentation for up to thirty (30) days in order to permit Sponsor to obtain appropriate intellectual property protection on any Confidential Information contained in the publication or presentation.

If the Study is part of a multi-site study, publication or presentation of the results of the Study conducted at the Institution shall not be made before the first multi-site publication by Sponsor. If there is no multi-site publication within eighteen (18) months after the Study has been completed or terminated at all Study locations, Investigator shall have the right to publish and or present the results of the Study generated or collected at Study Site(s) (but not the results of any other Study location), subject to the review requirements above.

Indemnification and Liability

Indemnification by Sponsor. Sponsor will indemnify, defend and hold harmless against any third-party claims Institution and its trustees, officers, agents, Study Personnel and Investigator (“**Institution Indemnitee(s)**”), including any (i) losses, costs, expenses (including reasonable attorney’s fees), and (ii) judgments or damages finally awarded by court order or finally paid in settlement or judgment ((i) and (ii) are collectively, “**Losses**”) incurred by an Institution Indemnitee arising from any third party claim based upon or caused by (a) the Study Drug and/or Study Device used in accordance with the Protocol and this Agreement during the course of the Study, (b) the performance of any procedure required by the Protocol that would not have been performed but for such subject’s participation in the Study that was performed in accordance with the Protocol and this Agreement, or (c) Sponsor’s use of Study Data or Study results or other intellectual property provided to it by Institution under this Agreement. Sponsor will not indemnify, defend or hold harmless Institution Indemnitees for Losses to the extent such Losses arise out of: (i) any failure of an Institution Indemnitee to conduct the Study in accordance with the Protocol, the terms of this Agreement or any applicable law, rule, guidance, or regulation; (ii) the negligence, recklessness or willful misconduct on the part of any Institution Indemnitee; or (iii) a breach of any of the Institution’s representations, certifications or obligations under this Agreement.

Responsibility of Institution. Institution agrees to accept responsibility for its own conduct and the conduct of the Institution Indemnitees with respect to losses to the extent that they are caused by (a) a breach of this Agreement by an Institution Indemnitee, (b) the negligence or willful misconduct of an Institution Indemnitee, or (c) any failure of an Institution Indemnitee to conduct the Study in accordance with the Protocol, the terms of this Agreement or any applicable law, rule, guidance, or regulation. Deviations from the Protocol and written instructions that occur when reasonably necessary to treat or manage an urgent or emergent condition of a Study subject shall not be deemed a failure to conduct the Study as addressed in subsection (c) above.

Indemnification Procedure. Institution Indemnitee will provide Sponsor with prompt written notice of any third-party claim for which indemnification is sought. Sponsor shall have sole control over the defense and settlement of any third-party claim provided it does so diligently, in good faith, and using reasonably experienced counsel with expertise in the relevant field, and the Institution Indemnitee will reasonably cooperate in the defense of such a claim. The Institution Indemnitee will not settle any third party claim against it without the Sponsor’s prior written consent, which consent shall not be unreasonably withheld. The Institution Indemnitee may, at its own expense, seek the advice of independent legal counsel.

Insurance

Each Party will maintain in effect appropriate levels of insurance or self-insurance for the duration of the Study in amounts sufficient to meet its liability obligations under this Agreement. Institution shall maintain general liability and professional liability insurance (or a similar form of self-insurance) with minimum amounts of $1,000,000 per occurrence and $2,000,000 annual aggregate. Institution will maintain, or will cause Investigator to maintain, adequate levels of medical malpractice insurance for the term of the Study. Sponsor shall maintain insurance or a similar form of self-insurance (including general liability, products liability and clinical trial liability coverage) in amounts of not less than $1,000,000 per occurrence and $3,000,000 annual aggregate. Each Party will provide certificates of insurance to the other Party upon reasonable request. Each Party’s insurance coverage will comply with applicable laws, rules, regulations and insurance guidelines.

Subject Injury

Sponsor will reimburse Institution or other medical provider for the reasonable and necessary costs of providing medical treatment for any adverse reaction or injury experienced by a Study subject, to the extent the adverse reaction or injury was arises directly from the use of the Study Drug and/or Study Device in accordance with the Protocol or procedures performed in accordance with the Protocol. Notwithstanding the foregoing, Sponsor’s obligation to reimburse Institution will not apply to the extent that such adverse reaction or injury is attributable to: (i) the negligence or misconduct of an Institution Indemnitee; (ii) an Institution Indemnitee's failure to adhere to the Protocol (it being understood, however, that emergency medical care shall not be deemed a violation of the Protocol), other written instructions provided by Sponsor, or applicable laws, rules, guidance, or regulations; or (iii) a pre-existing medical condition or underlying disease of the Study subject.

Use of Name.

Neither Party will use the name of the other Party or the other Party’s employees or any of their trademarks in any advertising, sales promotional material, or press release without the other Party’s prior written approval, except to the extent such disclosure is reasonably necessary for: (i) regulatory filings, including filings with the U.S. Securities and Exchange Commission or the FDA (or any equivalent oversight body in a country other than the United States); (ii) prosecuting or defending litigation; (iii) complying with applicable laws and regulations, and (iv) compliance with institutional regulations applicable to research. Notwithstanding the foregoing, the Parties shall have the right to post publicly registered information about the Study on their publicly accessible websites.

Relationship.

For the purposes of this Agreement, the Parties are independent contractors and nothing contained in this Agreement will be construed to place them in the relationship of partners, principal and agent, employer and employee or joint venturers. Neither Party will have the power or right to bind or obligate the other Party, or hold itself out as having such authority.

Term and Termination

Term. Unless terminated earlier by written notice of one Party to the other in accordance with Section 16.2, this Agreement will expire upon the later of the date on which: (i) Sponsor has received all properly completed CRFs from Institution; (ii) Institution has resolved all data clarification queries, and submitted the closeout reports to the IRB and to Sponsor to Sponsor’s satisfaction; (iii) all Institution and Study Site(s) closeout activities have been completed; and (iv) Sponsor has made all payments and reimbursements and collected all refunds due under this Agreement.

Termination.

### This Agreement may be terminated by Sponsor at any time for any reason upon thirty (30) days written notice with or without cause. Institution may terminate this Agreement if it is determined by the Internal Revenue Service or any other federal agency or instrumentality that the provisions of this Agreement are not in compliance with the requirements of Rev. Proc. 2007-47, if the IRB or any regulatory authority fails to provide its approval for the Study or otherwise suspends or terminates a Study approval or if Sponsor is in breach and said non-compliance or breach has not been cured within thirty (30) days of the Sponsor receiving notice from the Institution of the alleged non-compliance or breach. Either party may terminate this agreement immediately if necessary in order to protect the health, safety or welfare of Study subjects with written notice to the other Party.

### Upon receipt of a notice of termination, Investigator and Institution shall immediately stop enrolling subjects in the Study. Institution and Investigator shall continue to perform the follow-up testing in accordance with the Protocol and provide the Study Data (including CRFs) required under the Study for subjects who were enrolled in the Study prior to the receipt of the notice of termination, unless instructed otherwise by Sponsor in writing. The terms of this Agreement shall continue to apply with respect to all such follow-up testing and data, and Institution and Investigator shall promptly respond to requests from regulatory authorities and Sponsor for information relating to the conduct of the Study. Notwithstanding anything to the contrary in this section, Sponsor, Institution and Investigator agree that any termination requested hereunder shall not commence until such date as subjects in the Study can be transitioned out of the Study without adverse medical effect to such Study subjects.

### Institution and Investigator shall comply with Sponsor’s instructions regarding the return of Confidential Information and Sponsor property to Sponsor. Upon termination, Sponsor shall reimburse Institution for the costs actually incurred up until the termination of the Study at Institution including all non-cancelable obligations made before receipt of notice of termination.

## Survival. Any provision hereunder which by its terms or nature is meant to be followed or performed following the termination or expiration of the Study or this Agreement will survive any such expiration or termination, including, but not limited to Sections 1.6, 3, 4, 5.2, 6, 7, 8, 9, 10, 11, 13, 14, 16, 19 and 21.

Entire Agreement; Amendments; Assignment.

Entire Agreement. This Agreement, including any attachments referenced herein and the Protocol constitute the entire, final, complete and exclusive understanding of Sponsor and Institution concerning the Study. If there is a conflict between the terms of this Agreement and the Protocol, the terms of this Agreement will govern, except for conflicts related to matters of medicine, science, safety and conduct of the Study, which will be governed by the terms of the Protocol. This Agreement may be executed in counterparts.

Amendment. No changes, amendments or alterations will be effective unless in writing and signed by both Parties. No waiver, expressed or implied, will be a continuing or subsequent waiver of the particular right or obligation. Any purported assignment or delegation by Institution or Investigator of this Agreement or their obligations under this Agreement will be void without Sponsor’s advance written consent.

Assignment. Sponsor may assign this Agreement and its rights and obligations hereunder (a) in connection with the transfer, whether by license or otherwise, or sale of all or substantially all of its rights to the Study Drug or Study Device, (b) to any of its Affiliates, or (c) to any external service providers such as clinical research organizations retained to assist Sponsor in managing and monitoring the Study. Sponsor shall provide Institution with prompt written notice following the assignment.

Severability.

Any provision in this Agreement determined by proper judicial authority to be invalid or unenforceable will be revised by agreement of the Parties to the extent necessary to avoid the remainder of the Agreement being invalid or unenforceable.

Notice.

Any notice or consent required to be given under this Agreement must be in writing and sent to the other Party either: (i) via overnight delivery or personal delivery, which will be deemed delivered one (1) business day after deposit with such carrier; or (ii) by PDF document via email which will be deemed delivered at the beginning of the next regular business day following successful transmission. Notices will include reference to the Study Protocol number and be forwarded to the appropriate contact indicated below:

If to Sponsor:

[Name]

[Address]

[Attention]

[Phone, if applicable]

[Fax, if applicable]

[Email, if applicable]

If to Institution:

[Name]

[Address]

[Attention]

[Phone, if applicable]

[Fax, if applicable]

[Email, if applicable].

Force Majeure.

If either Party’s performance of this Agreement is prevented, restricted or delayed (either totally or in part) for reasons beyond the affected Party’s reasonable control and is not due to the action or inaction of such Party, the affected Party will, upon giving notice to the other Party, be excused from such performance to the extent of such prevention, restriction or delay; provided, that, the affected Party will use commercially reasonable efforts to avoid or remove such causes of non-performance and will continue its performance whenever such causes are removed.

Governing Law.

The Parties agree to be silent.

**IN WITNESS WHEREOF**, the Parties have entered into this Agreement as of the Effective Date by their duly authorized representatives.

|  |  |
| --- | --- |
| **INSTITUTION**By: Name Title: Date:  | **SPONSOR**By: Name Title: Date:  |

Read & Acknowledged

**INVESTIGATOR:**

By:

Title:

**EXHIBIT A**

**BUDGET AND PAYMENT SCHEDULE**