**CLINICAL STUDY AGREEMENT**

This CLINICAL STUDY AGREEMENT (**“Agreement”**) is made effectiveas of the **[NUMBER]** day of **[MONTH]**, **[YEAR]** (the **“Effective Date”**), and is by and among SPONSOR\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, a \_\_\_\_\_\_\_\_\_\_\_ corporation, with offices at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (**“SPONSOR”**) and **[INSTITUTION NAME]**, a [ ] corporation with offices at **[ADDRESS]** (**“Institution”**).

 WHEREAS, SPONSOR\_\_\_\_\_\_\_\_\_\_\_\_ intends to conduct a Single center [multi-center] clinical study (as defined below) of **[NAME OF DEVICE]** (**“Study Device”**).

 WHEREAS, the Institution has appropriate facilities and personnel and the Principal Investigator and co-investigators (as defined below) have the qualification, training, knowledge and experience necessary to conduct such a clinical study.

 NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

# Scope of Work.

## Conduct of the Study. As part of a multi-center clinical study, the Institution, the Principal Investigator and co-investigators shall conduct the clinical study entitled **[INSERT PROTOCOL NAME]** (the **“Study”**) in accordance with this Agreement, incorporated by reference herein (the **“Protocol”**), and the investigator’s brochure for the Protocol (the **“Investigator’s** **Brochure”**), as each may be amended, and all applicable laws, rules, regulations and guidelines relating to the conduct of clinical investigations, and good clinical and medical practice (collectively, **“Applicable** **Laws”**). For purposes of this Agreement, the term “Institution” shall include all employees, executives, officers, directors, faculty, staff and other authorized agents of the Institution.

# **The Principal Investigator and Co-investigators**. For sake of clarity, the Principal Investigator and co-investigators are employees of Institution or are under contract with the institution. The Principal Investigator will be named in Exhibit A. The Principal Investigator is the lead researcher at the institution responsible for this Study. The Principal Investigator represents and certifies that he or she has read and understands the Investigator’s protocol and brochure. The Principal Investigator is not a party but must read, sign and acknowledge the entire agreement. During the Study, the Institution shall immediately notify SPONSOR in writing at such time as it becomes aware that the Principal Investigator plans to leave the Institution or shall be unable to complete the Study. If the Institution and SPONSOR are unable to agree on an acceptable substitute investigator within fifteen (15) business days following such notice, SPONSOR may terminate this Agreement pursuant to Section 24.

# **Representations and Covenants**. The Institution and (to the extent that such representations and covenants relate to the Principal Investigator) the Principal Investigator each make certain representations, certifications and covenants to SPONSOR, as follows:

## the Principal Investigator is, and at all times during the course of the Study shall be, qualified by training and experience with appropriate expertise to conduct the Study;

## the Institution and the Principal Investigator have, and at all times during the course of the Study shall have, the appropriate licenses, approvals and certifications necessary to safely, adequately and lawfully perform the Study;

## none of the Institution, the Principal Investigator, or any other person who assists in performing the Study is subject to any conflicting obligations or has any financial or other interest in the outcome of the Study or has entered into any contract with respect to the Study that might interfere with the performance of the Study or that might impair the acceptance of the resulting data by the FDA or that might create a conflict of interest;

## the Institution is not currently using, and shall not use the services of any person who assists in performing the Study, including the Principal Investigator, who is debarred or proposed for debarment under the Federal Food, Drug, and Cosmetic Act, as amended, or otherwise disqualified or suspended from performing a clinical research study or otherwise subject to any restrictions or sanctions by the FDA or any other governmental or regulatory authority or professional body with respect to the performance of scientific or clinical investigations. The Institution will promptly notify SPONSOR if any person who assists in performing the Study becomes so debarred; and

## the Institution and the Principal Investigator have been selected to conduct the Study because of their experience, expertise and resources and not, in any way, as an inducement to, or in return for, past, present or future prescribing, purchasing, recommending, using, dispensing or granting preferential formulary status for any SPONSOR product.

## Institution and Principal Investigator shall be responsible for the conduct and supervision of all Institution's employees, agents and contractors performing services in connection with the Study ("Study Personnel")

# **Facilities**. The Institution and the Principal Investigator shall conduct the Study at the Institution, or such other facilities as SPONSOR and the Institution may agree in writing (the **“Facility”**). The Institution shall make available all personnel, facilities and resources necessary to efficiently and expeditiously accomplish its responsibilities under this Agreement.

# **Subject Enrollment and Informed Consent**.

## **Subject Enrollment**. The Principal Investigator shall enroll subjects into the Study in accordance with Exhibit A and Exhibit B, as described below (each a **“Subject”**). The Principal Investigator shall use all reasonable efforts to complete enrollment prior to any Subject Enrollment Closing Date set forth in writing to the Principal Investigator by SPONSOR. The Study period may be extended or shortened and the number of Subjects the Institution may enroll in the Study may be changed at SPONSOR’s sole discretion. The Institution acknowledges and agrees that if the Study is part of a Multi-Center Study, that when the enrollment goal for such Multi-Center Study as a whole is reached, enrollment will be closed at all sites, including the Institution, regardless of whether the Institution or any other site has reached its individual enrollment goal.

## **Informed Consent**. The Principal Investigator shall obtain the informed consent of each Subject prior to any screening or participation in the Study using the Informed Consent Materials (as defined in Section 10.3) and in accordance with Applicable Laws. Each Subject shall complete an informed consent form that has been reviewed and approved in advance by SPONSOR and by an institutional review board approved by the Institution that complies with the requirements of 21 C.F.R. Part 56 (**“IRB”**).

## **Adverse Events**. The Institution and Principal Investigator shall notify SPONSOR of any information concerning any serious or unexpected event, injury, toxicity or sensitivity reaction, and the severity thereof, associated with any Study or any Study Device in accordance with such SPONSOR guidelines for each Study with respect to the reporting of adverse Subject experiences as SPONSOR may supply in writing to the Institution from time to time.

# **Compensation; Fair Market Value**.

# 6.1 **Compensation.** For the services to be rendered hereunder, SPONSOR shall pay the Institution in accordance with the budget, payment schedule and procedures set forth in Exhibit A. The parties acknowledge that the amounts to be paid by SPONSOR under this Agreement are reasonable compensation for the work performed and that neither the Institution nor the Principal Investigator has received any other compensation or other inducement in connection with this Agreement or its participation in the Study. Any amounts paid by SPONSOR to the Institution for services that have not been performed, or expenses that have not been incurred, under this Agreement shall be promptly refunded to SPONSOR upon the expiration or termination of this Agreement or earlier at the written request of SPONSOR. Except with respect to those expenses reimbursable under Sections 19 and 24.4, the Institution acknowledges and agrees that the payments made by SPONSOR under this Section 6 represent SPONSOR’s total obligations under this Agreement, and fully cover the costs of conducting the Study, except for the cost of the device. Accordingly, the Institution shall not submit claims to, or otherwise seek reimbursement from, Medicare, Medicaid or any other third party payer, whether public or private, for any costs covered by payments made or services provided by SPONSOR under this Agreement. For products and devices received hereunder, the Institution shall pay SPONSOR in accordance with Exhibit C.

# 6.2 **Fair Market Value**. SPONSOR, Institution, and Principal Investigator acknowledge and agree that the compensation and support provided by SPONSOR to Institution and Principal Investigator pursuant to this Agreement, represents the fair market value for the services conducted by Institution and Principal Investigator, has been negotiated in an arms-length transaction, and has not been determined in a manner that takes into account the volume or value of any referrals or other business otherwise generated between SPONSOR, Institution, and Principal Investigator. If Principal Investigator or any Study Personnel providing services hereunder is a member of a committee for any entity that sets formularies or develops clinical guidelines, then, during the term of the Study and for a period of two (2) years thereafter, Institution shall require Principal Investigator and such Study Personnel to (a) disclose such Principal Investigator's and Study Personnel's involvement with SPONSOR’s Study to such committee; and (b) comply with any procedures set forth by such committee with respect thereto.

# **Financial Disclosure and Reporting**.

# 7.1 **Financial Disclosures by Principal Investigator.** At SPONSOR’s request, the Principal Investigator shall promptly provide to SPONSOR financial disclosure statements in compliance with 21 C.F.R. Part 54, in the form required by SPONSOR and executed by the Principal Investigator and any sub-investigators and such other financial information as SPONSOR may reasonably request. During the term of Study and for a period of one (1) year thereafter, the Principal Investigator and any sub-investigators shall promptly notify SPONSOR of any changes to such financial information.

# 7.2 **Financial Disclosure by SPONSOR**. Institution and Principal Investigator understand that SPONSOR is required pursuant to applicable law requiring financial transparency, including but not limited to the Physicians Payment Sunshine Act and its implementing regulations (the "Sunshine Act") to account for direct fees and pass-through expenses and other transfers of value paid on SPONSOR's behalf to covered recipients. Institution and Principal Investigator each agrees to keep complete and accurate records regarding all payments and other transfers of value made in connection with the Study performed pursuant to this Agreement. Institution and Principal Investigator shall provide SPONSOR with information regarding any and all such payments and transfers of value that Institution makes on SPONSOR's behalf in a written form acceptable to SPONSOR. The information shall be submitted to SPONSOR no later than thirty (30) days after the payment or transfer of value was made, either in writing to:[Insert address where it should be sent]. INSTITUTION agrees that SPONSOR may disclose certain information relating to such payments or transfers of value provided to covered recipients and acknowledges that such information may become public record.

# **Study Device**. The Study Device shall only be used as described in the Protocol and in compliance with Applicable Laws. The device has not been cleared by FDA for the indication under investigation in the Study. The Institution shall maintain complete and accurate records relating to the storage, inventory, disposition of the Study Device supplied to the Institution as set forth in Section 10.1.

# **Disclaimer**. Without limiting SPONSOR’s obligations under THIS AGREEMENT, SPONSOR DOES HEREBY DISCLAIM ANY AND ALL ADDITIONAL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, WITH RESPECT TO THE STUDY DEVICE, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OR THAT THE USE OF THE STUDY DEVICE FOR PURPOSES OTHER THAN SPECIFIED IN THIS AGREEMENT WILL NOT INFRINGE THE rightS, PATENT OR OTHERWISE, OF ANY THIRD PARTY.

# **Records; Reports; and Regulatory Assistance**.

## **Study Documentation**. The Institution and the Principal Investigator shall prepare, maintain and retain complete, current, accurate, organized and legible Study Documentation (as defined below) in a manner acceptable for the collection of data for submission to, or review by, the FDA and other regulatory or governmental authorities, and in full compliance with the Protocol and all Applicable Laws. For purposes of this Agreement, “Study Documentation” includes all records (related to the Study Device or Protocol), accounts, notes, reports and data, collected, generated or used in connection with the Study, whether in written, electronic, video or other tangible form, including all recorded original observations and notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the Study. The Principal Investigator and/or Institution will conduct data entry activities, which shall include entry of Subject data after Subject visit and response to queries, within the timelines provided by SPONSOR. For studies using web based electronic data capture technology (“**EDC**”), data will be entered in the EDC system at the Study site. Trained Study personnel will be responsible for entering data on the observations, tests and assessments specified in the Protocol into the EDC system and according to the CRF (as defined in Section 10.2). The CRF instructions will also provide the Study site with data entry instructions. Data entered in the EDC system will be automatically saved to a central database and changes tracked to provide an audit trail. When data have been entered, reviewed, edited, and Source Data Verification (“**SDV**”) performed, the Principal Investigator will be notified to sign the CRF electronically as per the agreed project process and data will be locked to prevent further editing. A copy of the CRF will be archived at the Study site. When an electronic invalidated system that allows retrospective entry or correction of medical records data is issued, Principal Investigator shall print, sign, date and file a copy of the relevant medical record each time a Subject visits a facility. The Principal Investigator’s electronic signature shall be the legally binding equivalent to a handwritten signature. If medical records of Study Subjects are held in a computerized medical system, such system must be in full compliance with the FDA rules on electronic records and signatures.

## **Provisions of Data and Reports**. The Institution shall provide to SPONSOR original case report forms (either in paper or electronic form if the Protocol calls for WBDC system) (collectively, **“CRFs”)** completed for each Subject participating in the Study and such other reports as and when required by the Protocol or Applicable Laws. The Institution shall provide the final CRFs required by the Study as set forth in Exhibit B or such later date as SPONSOR may require.

## **Institutional Review Board**. The Institution shall provide to SPONSOR documentation verifying review and approval by the IRB of (i) the information to be provided to potential Subjects of the Study to secure their informed consent, including information about any compensation being provided to Subjects for participation in the Study (**“Informed Consent Materials”**), (ii) the Protocol, (iii) the Investigator’s Brochure and (iv) amendments to any of the foregoing. The Institution shall ensure that the IRB continues to monitor the Study during the term of this Agreement in accordance with Applicable Laws and in any event at least once per year and shall provide to SPONSOR documentation of the IRB’s continuing review contemporaneously therewith.

## **Regulatory Assistance**. At the request and expense of SPONSOR, the Institution and the Principal Investigator shall: (a) assist SPONSOR in the preparation and submission of investigational new Device applications, new Device applications, any other premarket or marketing applications relating to the Study or the Study Device, and any amendments or supplements to the foregoing; (b) attend meetings with the FDA and other regulatory or governmental authorities regarding such applications and the associated approvals; and (c) provide such other reasonable assistance as SPONSOR may request in connection with regulatory matters relating to the Study or the Study Device.

# **Audit and Review**. SPONSOR or its authorized representatives shall have the right, upon advance written notice, at SPONSOR’s expense, and during regular business hours, to: (a) audit all Facilities used in performance of the Study; (b) monitor the conduct of the Study; (c) review, copy and audit all Study Documentation, any other books, records, data and Work Product (as defined in Section 14.4) relating to the Study or the IRB, and all required licenses, certificates and accreditation; (d) study, inspect and test all Study Devices after explant (or the Study devices can be sent back to the Sponsor for inspection); and (e) interview the Principal Investigator and other persons who assisted in performing the Study. Subject’s medical records shall be made available to SPONSOR.

# **Changes to the Protocol**. No change in the Protocol shall be made by the Institution or the Principal Investigator, subject to any Applicable Laws relating to the safety of Subjects that require a deviation from the Protocol, in which case the Institution shall promptly notify SPONSOR and the IRB of the nature of the deviation and the facts necessitating such deviation as soon as the facts are known to the Institution. SPONSOR may at any time make changes in the Protocol upon five (5) days’ advance written notice to the Institution; provided, however, that, unless the changes are required by Applicable Laws, do not materially increase the cost of performance of the Study by the Institution or are otherwise agreed to by the Institution, the Institution may terminate this Agreement pursuant to Section 24.

# **Regulatory Inspections**. If any governmental or regulatory authority (a) contacts the Institution or the Principal Investigator with respect to the Study, (b) conducts, or gives notice of its intent to conduct, an inspection at any Facility or (c) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of the Institution, the IRB or the Principal Investigator that could reasonably be expected to impact any data or clinical activity under the Study, then the Institution shall promptly notify SPONSOR of such contact or notice. SPONSOR shall have the right to be present at and to participate in any such inspection or regulatory action with respect to the Study. The Institution shall provide SPONSOR with copies of all pertinent information and documentation issued by any governmental or regulatory authority and any proposed response. SPONSOR shall have the right in advance to review and comment on any responses that pertain to the Study. No such response shall contain any false or misleading information with respect to the Study, the Study Device or SPONSOR.

# **Ownership of Materials, Intellectual Property and Work Product.**

## **Materials.** SPONSOR shall own all right, title and interest (collectively, **“Rights”**) in and to any equipment, materials, methods, documents, data, software and information supplied by or on behalf of, or purchased at the expense of, SPONSOR (collectively, **“Materials”**) in connection with the Study, unless specifically agreed to otherwise by SPONSOR in writing. To the extent SPONSOR supplies computers, Institution agrees that no software may be installed unless there is agreement in writing that such software is required to conduct the Study. The Institution shall make all reasonable UCC or other filings necessary to secure and evidence SPONSOR’s ownership of the Materials as and when requested in writing and reasonably reimbursed by SPONSOR. The Institution shall: (a) use the Materials only for the purposes described in the Protocol or such other purposes as SPONSOR may approve in writing, (b) restrict access to and use of the Materials to the Principal Investigator and other personnel for whom such access and use is required to conduct the Study and (c) deliver the Materials to SPONSOR or its designee at SPONSOR’s reasonable expense on the earlier of the (i) completion of the Study, (ii) the termination or expiration of this Agreement, (iii) the Institution’s participation in the Study, or (iv) as otherwise requested in writing by SPONSOR.

## **Retained Rights**. Each party shall retain all Rights in any patent, patent application, trade secret, know-how and other intellectual property that was owned by such party prior to the Effective Date of this Agreement and no license grant or assignment, express or implied, by estoppel or otherwise, with regard thereto is intended by, or shall be inferred from, this Agreement.

## **Inventions.** SPONSOR shall own all Rights in and to each invention, discovery, know-how, trade-secret and other intellectual property, including improvements, whether patentable or not, that is conceived, reduced to practice or otherwise made by the Institution, the Principal Investigator or any other person (other than SPONSOR) who assists in performing the Study (whether solely or jointly with others) (each, an **“Inventor”**) as a result of or in connection with the Study or the performance of obligations under this Agreement in accordance with the Protocol, including any patent, trade secret, trademark, or other proprietary right with respect thereto (collectively, the **“Inventions”**). The Institution shall promptly cause each Inventor to take any actions necessary to assign and transfer all Rights in each Invention to SPONSOR, at SPONSOR’s reasonable expense, including disclosing to SPONSOR in writing the conception, reduction to practice or making of such Invention, and, without additional consideration and at SPONSOR’s reasonable expense, assigning and transferring to SPONSOR all Rights to patents, patent applications and Rights to file for patent protection for such Invention throughout the world.

## **Work Product**. The Institution shall fully disclose to SPONSOR all work, reports, writings, designs, methods, computer software and data recorded in any form, including but not limited to Study Documentation, that are created, developed, written, conceived or made by the Institution, the Principal Investigator or any other person (whether solely or jointly with others) as a result of or in connection with the Study or the performance of their obligations under this Agreement in accordance with the Protocol (collectively, **“Work** **Product”**). The Institution and the Principal Investigator each agree that all Work Product (other than a Subject’s primary medical records and any articles or presentations that are published or made in accordance with Section 17) that is copyrightable subject matter shall be considered “work made for hire” within the meaning of the copyright laws of the United States and that SPONSOR is and shall be the sole author of such Work Product and the sole owner of all Rights therein. In the event that any such Work Product is deemed for any reason not to be a “work made for hire,” the Institution will irrevocably assign, and the Institution shall cause the Principal Investigator and each Inventor to irrevocably assign, to SPONSOR, at SPONSOR’s expense, all of their respective Rights worldwide in and to such Work Product. Such assignments shall include the right to all causes of action for copyright infringement of any such Work Product, including the right to institute, process, defend and settle any suit or other legal or administrative proceeding, to enjoin infringement or misappropriation of such Work Product, together with the sole right to any resulting recovery of damages, royalties, profits, legal fees and costs.

## **Assistance.** The Institution shall, and shall cause the Principal Investigator and any Inventor to, where applicable and consistent with the requirements of this Agreement: (a) execute all documents and perform all acts deemed necessary by SPONSOR to evidence SPONSOR’s ownership of any Invention and Work Product (including the making of any biological deposits) and (b) assist SPONSOR in preparing, prosecuting, obtaining, registering, maintaining, defending and enforcing, at SPONSOR’s sole expense (for actual costs incurred), discretion and exclusive control, all United States patents (including any divisions, continuations, continuations-in-part, reissues, renewals, extensions or the like of any such patent) and any foreign patents or equivalents thereof (including certificates of invention), copyrights, trade secret rights and other proprietary Rights in and to the Inventions and the Work Product in any and all countries as may be determined by SPONSOR.

## **Attorney-In-Fact.** The Institution and the Principal Investigator each hereby irrevocably appoints SPONSOR, and the Institution shall cause each Inventor or any other person, where applicable, irrevocably to appoint SPONSOR, as attorney-in-fact for the purpose of executing such documents in their respective names as may be necessary or desirable to carry out the purposes of Sections 14.1 through 14.5.

## **Government-Funded Activities**. The parties hereto agree that all activities under this Agreement (**“Agreement** **Activities”**) shall fall outside the planned and committed activities of any government-funded project undertaken by the Principal Investigator (**“Government-funded Activities”**) and shall not diminish or distract from the performance of such Government-funded Activities within the meaning of 37 C.F.R. § 401.1(a)(1), and, therefore, that any Invention made hereunder shall not be subject to the conditions of 37 C.F.R. Parts 401 and 404. In the event that Agreement Activities shall be found to be Government-funded Activities, the Institution, Principal Investigator and any other Inventor shall take all actions necessary to retain title to any Invention made under this Agreement, including those required by 37 C.F.R. §§ 401.14(c)(1), (2) and (3). In the event that any Inventions or Work Product conceived or reduced to practice, made or developed by any Inventor hereunder are controlled by federal law in accordance with 37 C.F.R. §§ 501.1 - 501.11 or any other Applicable Laws that would preclude SPONSOR from obtaining the Rights to such Inventions or Work Product under Sections 14.1 through 14.6, the Institution and the Principal Investigator shall and do hereby, and the Institution shall cause each other Inventor to: (a) secure such waivers and releases available or permitted under applicable laws to enable SPONSOR to obtain such Rights; and (b) if such waivers and releases are not available or permitted, grant to SPONSOR (or its designee) irrevocable, worldwide, exclusive, fully-paid, royalty-free right and license, with right to sublicense (or such other similar Rights to the maximum extent permitted by applicable laws), to exploit such Invention or Work Product, subject to the right of the U.S. Government to retain an irrevocable, royalty-free right to use such Invention or Work Product throughout the U.S. Government.

# **Confidential Information.**

## **Definition**. For purposes of this Agreement, **“Confidential Information”** means any information of SPONSOR, whether of a technical, business or other nature, including information that relates to SPONSOR’s trade secrets, products, Study Device, promotional material, developments, proprietary rights or business affairs, together with any Inventions, Work Product and all other written information, data and results collected, prepared, developed or generated by the Institution, the Principal Investigator and any other person pursuant to or in contemplation of this Agreement, including, subject to applicable laws and regulations, this Agreement. This Section 15 is subject to the Institution and the Principal Investigator’s publication rights as set forth in Section 17. Confidential Information does not include any information that:

### the Institution or the Principal Investigator can prove was known prior to the date of this Agreement and was not subject to any confidentiality restrictions;

### the Institution or the Principal Investigator can prove was lawfully obtained from a third party without breach of any obligation of confidentiality;

### 15.1.3 is or becomes part of the public domain through no act or violation of any obligation of the Institution or the Principal Investigator; or

###  (For the avoidance of doubt, when SPONSOR lists or discloses any non-confidential information relating to the Study Device or the Study in a clinical trial registry or clinical results database, any aspects or details of Confidential Information concerning the Study Device or the Study that are not listed or disclosed in such registry or database shall not be deemed to be or become part of the public domain.)

### 15.1.4 is independently developed by the Institution or the Principal Investigator, as shown by documentary evidence.

## **Non-Disclosure.** Subject only to Section 15.4, for a period of five (5) years after the expiration or termination of this Agreement, the Institution and the Principal Investigator shall not, without SPONSOR’s prior written consent or as may be permitted by this Agreement, disclose to any third party any Confidential Information, and shall use such Confidential Information solely for purposes of performing its obligations under this Agreement. The Institution shall restrict the dissemination of Confidential Information to only those persons within the Institution who have a need to know, and shall ensure that they are aware of the obligation of confidentiality required by this Agreement. The Institution and the Principal Investigator shall use at least the same care and discretion in maintaining the confidentiality of the Confidential Information as each uses with its most sensitive confidential information. The Institution or the Principal Investigator, as applicable, shall notify SPONSOR promptly upon the Institution or the Principal Investigator’s discovery of any loss or compromise of the Confidential Information. Upon the termination or expiration of this Agreement or upon SPONSOR’s earlier written request, the Institution or the Principal Investigator shall promptly return to SPONSOR all Confidential Information at SPONSOR’s reasonable expense. Upon the termination of the Institution’s participation in the Study or upon SPONSOR’s earlier written request, the Institution and the applicable Principal Investigator shall promptly return to SPONSOR all Confidential Information related to the Study at SPONSOR’s reasonable expense. In either case, the Institution shall have the right to retain, subject to the other provisions of this Section 15.2, the original copies of each Subject’s primary medical records.

## **External Discussions**. THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR AGREE THAT, BY ENTERING INTO THIS AGREEMENT, THEY HAVE ASSUMED A RELATIONSHIP OF TRUST AND CONFIDENCE WITH SPONSOR PURSUANT TO WHICH THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR WILL HAVE ACCESS TO CONFIDENTIAL INFORMATION. ACCORDINGLY, THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR AGREE THAT, EXCEPT AS EXPRESSLY PERMITTED UNDER THIS SECTION 15, THEY SHALL NOT DISCUSS THE STUDY OR THE STUDY DEVICE WITH ANY PERSON NOT PERFORMING SERVICES UNDER THIS STUDY FOR ANY REASON AND SHALL NOT EXPRESS ANY OPINION THAT IS INFORMED, IN WHOLE OR IN PART, WHETHER DIRECTLY OR INDIRECTLY, BY ACCESS TO THE CONFIDENTIAL INFORMATION. FOR THE AVOIDANCE OF DOUBT, NEITHER THE INSTITUTION NOR THE PRINCIPAL INVESTIGATOR SHALL DISCUSS THE STUDY OR THE STUDY DEVICE WITH ANY FINANCIAL, SECURITIES OR INDUSTRY ANALYST OR WITH THE MEDIA.

## **Exceptions to Non-Disclosure**. Notwithstanding Sections 15.2 and 15.3, if the Institution or the Principal Investigator are legally required to disclose Confidential Information or results of the Study, the Institution or the Principal Investigator, as applicable, shall promptly notify SPONSOR in writing, but no less than five (5) business days, prior to making the required disclosure. If such disclosure is required pursuant to a lawful judicial or government order, the Institution and the Principal Investigator shall permit SPONSOR to defend against any such order of disclosure and the Institution shall assist, at SPONSOR’s expense, in such defense to the extent permitted by applicable laws. If the Institution or the Principal Investigator is thereafter or otherwise required to disclose any Confidential Information, the Institution or the Principal Investigator, as applicable, shall craft such disclosure as reasonably requested by SPONSOR so that such disclosure shall contain only such Confidential Information as is required by applicable laws. Nothing contained herein shall prohibit the Institution or the Principal Investigator from immediately disclosing results of the Study to the extent necessary to prevent or mitigate a serious health hazard; provided, however, that the Institution or the Principal Investigator, as applicable, shall notify SPONSOR prior to making such a disclosure and promptly after it has made such a disclosure.

# **Privacy and HIPAA.**

## **Covered Entities**. The Institution and the Principal Investigator each represent, certify and covenant that it is a “Covered Entities” under the provisions of the Health Insurance Portability and Accountability Act of 1996 and any regulations and official guidance promulgated thereunder (**“HIPAA”**). The Institution and the Principal Investigator shall handle all Study Documentation (including Subjects’ medical records) in accordance with HIPAA requirements and all other Applicable Laws and shall ensure that they obtain from each Subject a valid authorization that complies with HIPAA and is, in form and substance, acceptable to SPONSOR, in order for the Institution and the Principal Investigator to provide SPONSOR with the Study Documentation and to satisfy their other obligations under this Agreement with respect to the Study Documentation.

## **SPONSOR Not Covered By HIPAA**. SPONSOR represents, warrants and covenants, and the Institution and the Principal Investigator acknowledge and agree, that no component of SPONSOR or any of its affiliates that will be performing any of SPONSOR’s obligations under this Agreement: (a) is a “Covered Entity,” (b) will become a “Business Associate” of a Covered Entity by performing its obligations under this Agreement or (c) is otherwise governed by HIPAA.

# **Publication and Use of Study Results**.

## **Study Data**. The Institution and the Principal Investigator acknowledge and agree that the data collected during the Study is confidential, and agree that premature disclosures of the data may be misleading. After the completion, or earlier termination, of the Study at all participating sites, SPONSOR shall conduct, or cause to be conducted, such analyses of the data resulting from each site participating in the Multi-Center Study (**“Multi-Center Study Analyses”**) and, if requested, deliver the results of such analyses (**“Multi-Center Study Results”**) to the Principal Investigator together with the underlying data relating only to Subjects enrolled in the Study at the Institution (**“Site Data”**), but not any other data and databases that are supplied, prepared, collected, developed or generated as a result of, in the performance of, or in connection with the Multi-Center Study at non Institution sites (**“Multi-Center Study Data”**); provided, however, that SPONSOR shall have the right to delay the delivery of the Multi-Center Study Results and the Site Data for up to 18 months for regulatory or intellectual property purposes. Further, SPONSOR, or its designee, shall have the right to coordinate one or more publications of the Study Results (each, a **“Publication”**). In case the Study is being conducted solely at the Institution, the SPONSOR will make the data available to the Principal investigator at the end of the study, provided the Principal Investigator and Institution maintain the data confidential at the request of the SPONSOR for up to 18 months for regulatory or intellectual property purposes.

## 17.2 **Publication and Use of Study Data**. The Principal Investigator may use the Multi-Center Study Results and/or the Site Datafor the limited purpose of his or her own research and academic analysis, provided that, subject to Section 17.3, neither the Institution nor the Principal Investigator shall make any publication or presentation with respect to the Multi-Center Study or the Studyor the respective results until the earlier of (i) the publication of the first Study Results Publication, or (ii) eighteen (18) months after the completion, or earlier termination, of the Study at all participating sites. In no event shall the Institution or the Principal Investigatorpublish, cause to be published or make any presentation disclosing the raw Site Data or any other Multi-Center Study Data (as distinguished from results of analyses of the Site Data and the Multi-Center Study Results) or make any publication or presentation that is false or misleading or that SPONSOR determines: (a) is not in accordance with this Section 17, (b) is not consistent with academic standards or (c) is for commercial purposes. Except as provided in this Section 17.2 with respect to the Principal Investigator, the Institution shall not make any publication or presentation with respect to the Study or the Multi-Center Study. In no event will the Institution or the Principal Investigator be so restricted after eighteen (18) months have elapsed since the completion of the Study at all participating sites.

## **SPONSOR Review**. The Institution and the Principal Investigator shall submit a copy of any proposed manuscript, abstract, presentation or other document with respect to the Study, including any Multi-Center Publication of which the Principal Investigator is an author, to SPONSOR for review and comment at least sixty (60) days prior to its submission for publication or presentation. No publication or presentation with respect to the Study shall be made unless and until all of SPONSOR’s comments on the proposed publication or presentation have been considered by the Principal Investigator and any Confidential Information has been removed; provided that any analyses performed by the Principal Investigator using any Multi-Center Study Analyses (or the Site Data)or that have been disclosed in a publication or presentation authorized pursuant to this Section 17 or pursuant to another clinical study agreement under the Study, shall not be deemed Confidential Information for purposes of this Section 17. If requested in writing by SPONSOR, the Institution and the Principal Investigator shall withhold material from submission for publication or presentation for an additional ninety (90) days to allow for the filing of a patent application or the taking of other measures to establish and preserve SPONSOR’s proprietary rights. To the extent that any provision of this Section 17 may be inconsistent in any respect with any statements about publication policy set forth in the Protocol, the provisions of this Section 17 shall control.

## **Authorship and Final Contents**. Subject to the foregoing, the authorship and final contents, including scientific conclusions and professional judgments, of any paper submitted about the Multi-Center Study or the Study by the Principal Investigator shall be determined by the Principal Investigator.

## **License to SPONSOR**. The Institution and the Principal Investigator agree that, if either publishes the results of the Multi-Center Study or the Study, SPONSOR is hereby granted an irrevocable, royalty-free license to make and distribute copies of such publication under any copyright privileges that the Institution and the Principal Investigator may have. SPONSOR also shall have the right to publish independently the results of the Multi-Center Study and the Study.The Institution and the Principal Investigator shall, in any agreement with a journal or other publisher to publish the results of the Multi-Center Study or the Study, use reasonable efforts to reserve expressly all copyright rights necessary to grant SPONSOR the license and rights contained herein.

## **Clinical Trial Registries and Clinical Results Databases**. Without limitation to any other right of SPONSOR hereunder, the Institution and the Principal Investigator acknowledge and agree that SPONSOR shall have the right to list the Multi-Center Study or the Study on one or more clinical trial registries and to publish the results of the Multi-Center Study or the Study in one or more clinical results databases.

#  **Use of Name; Advertising.**

## **Use of Name.** Subject to Applicable Laws, none of the Institution, the Principal Investigator or SPONSOR shall mention or otherwise use the name, trademark, trade name or logo of any other party in any publication, press release or promotional material with respect to the Study without the prior written approval of such other party; provided, however, that SPONSOR shall have the right to identify the Institution as the site at which the Study was conducted and to identify those individuals responsible for conducting the Study. The Institution may use the name of SPONSOR and the title of the Study for internal purposes, including, but not limited to, acknowledging the Principal Investigator’s work.

## **Advertising**. Neither the Institution nor the Principal Investigator shall issue to the public any information or statement through the press or any other media, including advertisements for the enrollment of Study Subjects, without the prior written permission of SPONSOR and the review and approval of the IRB.

# **Indemnification , Insurance and Limitation of Liability.**

## **Indemnification by SPONSOR.** SPONSOR shall defend, indemnify and hold harmless the Institution its officers, directors and employees, Principal Investigator and Study Personnel (collectively, the **“Institutional** **Indemnified** **Parties”**) in connection with any third party claim, action or demand (collectively "Claims") for all costs, expenses and liabilities ("Losses") resulting from: (i) SPONSOR Indemnified Parties’ negligence or willful misconduct; (ii) SPONSOR 's breach of this Agreement; (iii) SPONSOR Indemnified Parties' failure to follow Applicable Laws; or (iv) bodily injury or death directly caused by the Study Device, provided that (i) the Study Device was used in accordance with this Agreement and the Protocol and (ii) such bodily injury or death did not result from (a) the negligence or willful misconduct of Institutional Indemnified Parties (b) the breach of this Agreement by Institution; or (c) Institutional Indemnified Parties' failure to follow Applicable Laws or prudent clinical practices. Notwithstanding the foregoing, SPONSOR’s indemnification obligations hereunder shall not apply to the extent such claims are caused by the matters contemplated in Section 19.2 below.

## **Indemnification by Institution**. Institution shall defend, indemnify and hold harmless SPONSOR and its officers, directors, agents, and employees ("SPONSOR Indemnified Parties") in connection with any Claim for all Losses resulting from (i) Institutional Indemnified Parties' negligence or willful misconduct; (ii) Institution's breach of this Agreement; (iii) failure by any Institutional Indemnified Parties to follow Applicable Laws or prudent clinical practices: or (iv) failure by any Institutional Indemnified Parties to follow the Protocol. Notwithstanding the foregoing, Institution’s indemnification obligations hereunder shall not apply to the extent such claims are caused by the matters contemplated in Section 19.1 above.

## **Reimbursement of Medical Expenses.** (a) Notwithstanding Section 19.1, SPONSOR shall reimburse the Institution for the direct, reasonable and necessary medical expenses incurred by the Institution for the treatment of any bodily injury that is a direct result of (a) the use of the Study Device in accordance with this Agreement, the Protocol and any other written instructions of SPONSOR or (b) any performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study if (i) the Institutional Indemnified Parties have complied with this Agreement, the Protocol and any written instructions of SPONSOR concerning the Study and (ii) all the requirements of informed consent have been complied with in accordance with Section 5.2.; (iii) such injury is not attributable to a pre-existing condition or underlying disease of the subject; or (iv) such injury is not attributable to the negligence or misconduct of the Institutional Indemnified Parties. SPONSOR will not provide compensation for lost wages or for any other damages, expenses or losses, or for medical expenses that have been covered by a Subject’s medical or other insurance, provided, however, SPONSOR understands and agrees that Subject is not required to file an insurance claim.

### (b) SPONSOR's agreement to pay Institution under this Section 19.3 is being provided as reasonable consideration for Study subjects willingness to participate in the Study, and does not constitute an admission of liability for any injury, which ultimately could be determined only through an adjudication process, or as a settlement or compromise of any potential future liability claim.

## **Effect of Termination or Expiration.** Termination or expiration of this Agreement or the Study shall not affect SPONSOR’s indemnification obligations to the Institutional Indemnified Parties with respect to any third party claim, action or demand resulting from the conduct of the Study prior to the Institution’s or the Principal Investigator’s first receipt of notice of termination. SPONSOR shall have no obligation under this Section 19 with respect to any activities performed by or on behalf of the Institution or the Principal Investigator after the receipt of such notice.

# 19. 5 **Indemnification Procedures.**

##  19.5.1 **Conditions of Indemnity**. The party claiming a right of indemnification or defense under this Agreement shall provide the indemnifying party prompt notice (in all events within twenty (20) days) of any such Claim, including a copy thereof, served upon it, and shall cooperate fully with the indemnifying party and its legal representatives in the investigation of any such Claim, at the indemnifying party’s expense; provided that the failure to provide such notice within such period shall not affect the indemnified party’s rights pursuant to this Section 19.5, except to the extent that the indemnifying party is actually prejudiced thereby. The indemnifying party shall have the right to exercise sole control over the defense and settlement of any such Claim, including the sole right to select defense counsel and to direct the defense or settlement of any such Claim; provided that the indemnifying party shall not enter into any settlement or admit fault or liability on the indemnified party’s behalf without the prior written consent of the indemnified party, which consent shall not be unreasonably withheld or delayed. The indemnified party shall have the right to select and to obtain representation by separate legal counsel. If the indemnified party exercises such right, all costs and expenses incurred by the indemnified party for such separate legal counsel shall be borne by the indemnified party. The indemnifying party shall be relieved of any indemnification obligation hereunder if any indemnified party (a) fails to follow the procedures set forth herein; (b) compromises or settles any Claim without indemnifying party's prior written approval; or (c) makes any admission or takes any other action with respect to any such Claim that, in indemnifying party's reasonable judgment, is prejudicial to the defense of such Claim, without indemnifying party's prior written approval.

## 19.5.2 **No Acknowledgement of Liability.** The assumption of the defense of a Loss by the indemnifying party shall not be construed as an acknowledgment that such party is liable to indemnify any indemnified party in respect of the Loss, nor shall it constitute a waiver by the indemnifying party of any defenses it may assert against the indemnified party’s claim for indemnification. If it is ultimately determined that the indemnifying party is not obligated to indemnify, defend or hold harmless the indemnified party from and against the Loss, the indemnified party shall reimburse the indemnifying party for any and all costs and expenses or other Losses incurred by the indemnifying party in its defense of the Loss with respect to such indemnified party.

# 19.6 **Insurance**.

19.6.1 **Insurance Coverage.** Institution (on its own behalf and on behalf of the Principal Investigator) shall maintain the following insurance coverages:

(i) professional liability insurance coverage of not less than three million dollars ($3,000,000) per occurrence and three million dollars ($3,000,000) in the aggregate; and

(ii) general liability insurance coverage of not less than three million dollars ($3,000,000) per occurrence and three million dollars ($3,000,000) in the aggregate.

19.6.2 **Policy**. Such coverage shall be primary to any insurance coverage that SPONSOR may maintain. The coverage shall remain in place throughout the term of the Study and, if a policy is a claims-made policy, for an additional three (3) years after completion of the Study.For clarity, the foregoing insurance requirements shall not in any way limit Institution's liability with respect to its indemnification or other obligations under this Agreement

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###  19.6.3 **Certification.** The Institution shall, at SPONSOR’s written request, have its insurance carrier or carriers, or with respect to a self-insurance program have an appropriate officer of the Institution, furnish to SPONSOR certificates that all insurance required under this Agreement is in force, such certificate to indicate any deductible and any self-insured retention. The Institution shall promptly provide SPONSOR with written notice of any cancellation, non-renewal, expiration or material modification of any required insurance or self-insurance.

###

# 19.7 **Limitation of Liability. EXCEPT FOR LIABILITY ARISING UNDER SECTION 16 (PRIVACY AND HIPAA ), SECTION 14 (OWNERSHIP), SECTION 15 (CONFIDENTIAL INFORMATION), AND EACH PARTY’S INDEMNITY AND DEFENSE OBLIGATIONS PURSUANT TO SECTION 19 FOR CLAIMS ASSERTED BY THIRD PARTIES, IN NO EVENT SHALL ANY PARTY HEREUNDER BE LIABLE TO ANY OTHER PARTY HEREUNDER FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING FROM OR IN RELATION TO THIS AGREEMENT, THE PROTOCOL OR THE STUDY DEVICE (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, BY STATUTE OR OTHERWISE). THIS LIMITATION SHALL APPLY EVEN IF SUCH PARTY HAS BEEN ADVISED OR IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES.**

# **Term**. This Agreement shall be effective as of the Effective Date and shall continue until the earlier of (i) the date that the final Study Documentation has been provided to SPONSOR following completion of the Study at all Study Sites, or (ii) the date that this Agreement is terminated in accordance with Section 24.

# **Termination**.

## **Right to Terminate or Suspend Study**. SPONSOR or the Institution may terminate or suspend any Study at the Institution’s facilities immediately upon written notice to the other for safety concerns or as otherwise required by Applicable Laws. Further, SPONSOR may immediately terminate or suspend any Study if such Study is terminated or suspended at other Study sites. SPONSOR may terminate the Institution’s participation in any Study, in its sole discretion, on written notice to the Institution. SPONSOR or the Institution may terminate the Institution’s participation in any Study in the event of material breach by the other of this Agreement, provided that the other is given written notice of the nature of the default and an opportunity to cure such default within a period of thirty (30) business days after the giving of notice. The Institution may terminate its participation in a Study, on written notice to SPONSOR, if such Study is suspended or terminated and not recommenced within ninety (90) days. Further, the Institution may terminate its participation in a Study if SPONSOR makes changes to such Study that are not required by Applicable Laws and not agreed to by the Institution or approved by the IRB and such changes materially increase the cost of performance of such Study by the Institution.

## **Right to Terminate Agreement**. SPONSOR may terminate this Agreement, in its sole discretion, on written notice to the Institution. SPONSOR or the Institution may terminate this Agreement in the event of material breach by the other of this Agreement, provided that the other is given written notice of the nature of the default and an opportunity to cure such default within a period of thirty (30) business days after the giving of notice.

## **Transition Upon Termination**. Upon notice of termination of the Study or this Agreement, the Institution shall immediately cease enrollment of Subjects into the Study and, at the election of SPONSOR, shall: terminate the Study with respect to the enrolled Subjects in an orderly and prompt manner, to the extent medically permissible, and pursuant to consultation with SPONSOR or SPONSOR’s clinical monitor, including, without limitation, any required follow-up treatment with previously enrolled Subjects. SPONSOR or its designee shall have the right to assume full control of the terminated Study and the Institution shall turn over all Study Documentation and materials in its possession associated with the Study, including all Work Product, Inventions and Materials, as expeditiously as possible, shall handle the Study Device in accordance with Section 8 and shall provide such other assistance as is necessary to ensure a smooth and orderly transition of the Study that will not involve any disruption of the Protocol. Upon notice of suspension of the Study, the Institution shall immediately cease enrollment of Subjects into the Study. SPONSOR shall reimburse Institution for all expenses incurred from such transition except for such transitions required due to an uncured breach of this Agreement by Institution.

## **Payment Owed**. Except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by the Institution, upon termination of this Agreement or the Institution’s participation in the Study, SPONSOR shall, upon receipt of applicable invoices and other supporting documentation satisfactory to SPONSOR: (a) reimburse the Institution for its reasonable and verifiable Study costs and reasonable un-cancelable Study costs or expenses incurred in connection with transfer of Subjects pursuant to Section 24.3 and (b) with respect to Subjects who have not completed the Study at the date of the termination, make payments to the Institution in accordance with Exhibit A for work already performed in accordance with the Study.

## **Final Accounting**. Within thirty (30) days after the termination of this Agreement, the Institution shall deliver to SPONSOR a final accounting of all Subjects participating in the Study and the visits completed in accordance with the Study during the term of this Agreement, and all reasonable direct costs incurred in connection with any transfer of the Study. Within thirty (30) days of delivery or receipt of the final accounting, either the Institution shall refund to SPONSOR any excess amounts paid by SPONSOR or SPONSOR shall pay any additional amounts owed to the Institution, as the case may be. SPONSOR or its designee shall have the right for a period of two (2) years after the payment of any transfer costs to audit the Institution’s books and records with respect to such accounting.

# **Independent Contractor**. In undertaking to perform the respective services hereunder, the Institution and the Principal Investigator are doing so as independent contractors, and not as employees or agents of SPONSOR. No party shall represent itself as an agent of any other party.

# **Assignment**. No party shall assign this Agreement or any rights or obligations hereunder without the prior written consent of the other parties, except that SPONSOR, without the consent of any other party hereto, may assign this Agreement and its rights and obligations hereunder (a) to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates, (b) in connection with the transfer, whether by license or otherwise, or sale of all or substantially all of its rights to the Study Device or (c) to any direct or indirect affiliate of SPONSOR.

# **Severability**. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, to the fullest extent permitted by Applicable Law and if the rights or obligations of any party will not be materially and adversely affected: (a) such provision will be given no effect by the parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect and (c) the parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the parties. To the fullest extent permitted by applicable law, the parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

# **Governing Law**. This Agreement shall be governed in accordance with the laws of the Commonwealth of Massachusetts without regard to the conflicts of laws, provisions or principles therein.

# **Notices**. Any notice, request or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if hand delivered or sent by an internationally recognized overnight delivery service, costs prepaid, or by facsimile (with transmission confirmed), addressed to the parties at:

If to SPONSOR, to: If to the Institution or the Principal Investigator, to:

|  |  |  |  |
| --- | --- | --- | --- |
| Address: | [Insert SPONSOR address] | Address: | [Insert Institution address] |
|  |  |  |  |
|  |  |  |  |
| Facsimile: | [INSERT SPONSOR facsimile] | Facsimile: | [Insert Institution facsimile] |
| Attention: | [Insert SPONSOR representative] | Attention: | [Institution representative] |

 or to such other address as the party to whom notice is to be given may have provided to the other parties in accordance with this Section 29. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed), or on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service, whichever is the earlier. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 29 is not intended to govern the day-to-day business communications necessary between the parties in performing their obligations under the terms of this Agreement.

# **Business Communications**. The Institution and the Principal Investigator consent to receive communications sent by or on behalf of SPONSOR via mail, e-mail and/or fax at the Principal Investigator and the Institution’s mailing address, e-mail address and fax number set forth below.

# If to Institution, to: If to the Principal Investigator, to:

# Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# E-mail address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ E-mail address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Facsimile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Facsimile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# **Survival**. The respective rights and obligations of the parties set forth in Sections 6 (other than the first sentence), 7-11, 13, 14, 16-22, 24, 29 and this Section 32 shall indefinitely survive the expiration or termination of this Agreement to the extent necessary to preserve such rights and obligations.

# **Entire Agreement**. This Agreement, together with the Exhibits hereto, constitutes the entire agreement among the parties hereto with respect to the subject matter of this Agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each party confirms that it is not relying on any representations, warranties or covenants of any other party except as specifically set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud.

# **Amendment**. Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each party.

# **Waiver**. A party’s failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing.

# **Inconsistency**. In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects (including Section 17), the terms of this Agreement shall prevail.

# **Construction**. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders, the word “or” has the inclusive meaning represented by the phrase “and/or” and the term “including” or “includes” means including, without limiting the generality of any description preceding such term. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. A reference in this Agreement to a Section or Exhibit is to the referenced Section or Exhibit of this Agreement. The wording of this Agreement shall be deemed to be the wording mutually chosen by the parties and no rule of strict construction shall be applied

# **Counterparts**. This Agreement may be executed in two or more counterpart copies, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument.

THIS AGREEMENT IS EXECUTED by the authorized representatives of SPONSOR and the Institution as of the date first written above.

|  |  |
| --- | --- |
| SPONSOR, Inc. | **[**NAME OF INSTITUTION**]** |
| Signature :  | Signature :  |
| Name :  | Name :  |
| Title : Date: …………………………………. | Title : Date: …………………………………. |
| PRINCIPAL INVESTIGATORREAD AND ACKNOWLEDGED |
| Signature :  |
| Name :  |
| Title :  |

Date: ………………………………….

**EXHIBIT A**

### **ENROLLMENT AND PAYMENT SCHEDULE**

### **[Note: This template is provided as a courtesy and is very dependent on the protocol, study design, duration and budget. More details may be necessary. The language should be adapted accordingly)**

1. **Principal Investigator and Enrollment**. The Principal Investigator for the Study is [INSERT NAME OF PI]. The Principal Investigator is asked to enroll up to [INSERT NUMBER] subjects during the open enrollment time period subject to increase or decrease based on study progress. Open enrollment is expected to run [INSERT NUMBER OF MONTHS].

2. **Consideration to Institution**. As payment in full for all services and tests provided under this Agreement, SPONSOR shall make the following payments to the fund specified in Section 2.1 of this Exhibit A.

2.1 Payment Information.

All payments shall be made by SPONSOR in U.S. Dollars to the following fund:

#### Fund Name: [ ]

Tax ID #: [ ]

Mailing address: [ ]

Attention: [ ]

* 1. Study Enrollment and Case Report Submission

Payment  per enrolled Subject will be made on a quarterly basis after SPONSOR’s (or its designee’s) receipt of all CRFs that are due at or shortly following the required visit, provided that the treatment rendered was consistent with the Protocol and this Agreement, and that all such CRFs are fully and accurately completed.

* 1. Payment Schedule

SPONSOR agrees to pay according to the following schedule:

* + 1. One (1) payment of $[INSERT AMOUNT] for non-refundable administrative study start-up fee.
		2. One (1) payment of $[INSERT AMOUNT] for initial IRB review upon SPONSOR’s receipt of IRB approval for the Study from the Institution and submission of IRB cost. Any additional IRB fees for continuing reviews, submission of amendments, and translations of the Informed Consent Form shall be submitted to SPONSOR as required.
		3. The following items will be submitted by the Institution to SPONSOR as applicable:
			1. Screen failures (i.e. after consent) will be reimbursed upon monitored and collected CRF documentation up to a maximum of $XXXX dependent on assessments completed and verified on CRFs. A maximum of XX Screen Failures per site subject to SPONSORs review.
			2. The rate for patient payment is as follows based on assessments completed and verified on CRFs:
		- One (1) payment up to of $[INSERT AMOUNT] for [PROTOCOL VISIT]
		- One (1) payment up to $[INSERT AMOUNT] for [PROTOCOL VISIT]
		- One (1) payment up to $[INSERT AMOUNT] for [PROTOCOL VISIT]
		- One (1) payment $[INSERT AMOUNT] for [PROTOCOL VISIT]
		- One (1) payment of $[INSERT AMOUNT] for [PROTOCOL VISIT]
		- One (1) payment $[INSERT AMOUNT] for [PROTOCOL VISIT]
		- One (1) payment of $[INSERT AMOUNT] for [PROTOCOL VISIT]
		- One (1) payment of $[INSERT AMOUNT] for [PROTOCOL VISIT]

The total per patient payment shall not exceed $[INSERT AMOUNT].

3. **Consideration to SPONSOR**. As payment in full for devices, Institution shall make the following payments as specified in Section 3.1 of this Exhibit A.

3.1 Payment Information. All payments shall be made by the Institution by check in U.S. Dollars payable as follows:

ATTN: Accounts Receivable

SPONSOR, Inc.

3.2 Compensation for Devices and Equipment.

3.2.1 Compensation for devices and equipment shall be in accordance with Exhibit C.

4. **Certain Billing**. Institution and Principal Investigator represent that in no event will either of them (individually or jointly) submit any charge to any governmental agency (including Medicare or a state agency, such as Medicaid) which reimburses for health care services, or any other payer, for any device, equipment, tests, or services that are provided by SPONSOR free of charge or that are reimbursed by SPONSOR under this Agreement.

5. **Tax Information**. Institution shall provide a signed W-9 (Request for Taxpayer Identification Number and Certification) upon execution of this Agreement.

**Principal Investigator should check only one of the following boxes:**

🞏 I will provide SPONSOR with a written statement that defines which tests and/or office visits are not routine for Subjects treated under the Study, and their associated costs.

🞏 I anticipate that there will be no additional costs associated with tests and/or office visits for Subjects treated in the Study.

Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**EXHIBIT B**

**PROTOCOL**

**EXHIBIT C**

**[ATTACH COPY OF QUOTATION(S)]**