Early Feasibility Study (EFS) Program: Master Clinical Trial Agreement (MCTA)

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Northwestern University
Piedmont Heart Institute
University of Pennsylvania
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*Disclaimer: This document is intended as an educational tool for sponsors and sites participating in clinical trials conducted through the FDA/CDRH EFS Program. It does not represent the official view of the U.S. Food and Drug Administration (FDA), the Center for Devices and Radiological Health (CDRH), or any part of the US Federal Government. No official endorsement of this document by the FDA or CDRH is should be inferred.

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MEDICAL DEVICE INNOVATION CONSORTIUM

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On behalf of the Medical Device Innovation Consortium Clinical Trial Science working group on Early Feasibility Studies

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EFS MASTER CLINICAL STUDY AGREEMENT

IMPORTANT NOTE: This Early Feasibility Study ("EFS") Master Clinical Trial Agreement template is provided by The Medical Device Innovation Consortium ("MDIC") as an educational tool. It is neither intended, nor should be considered, to be legal advice. Applicable laws may vary in different states. Also, federal and state laws governing clinical studies are subject to change and to varied interpretations by courts in different jurisdictions. Each Institution and Sponsor entering into a clinical study agreement should consult with its own counsel to obtain legal advice on contracts for clinical studies.

This MASTER CLINICAL STUDY AGREEMENT (**"Agreement"**) is made effective as of the **[NUMBER]** day of **[MONTH]**, **[YEAR]** (the **"Effective Date"**), and is by and between **[SPONSOR NAME]**, a [ ] corporation, with offices at **[ADDRESS]** (**"SPONSOR"**) and **[INSTITUTION NAME]**, a [ ] corporation with offices at **[ADDRESS]** (**"Institution"**).

WHEREAS, SPONSOR is engaged in the development of medical device technologies, and in connection therewith intends to conduct one or more early feasibility clinical studies (each a **"Study" or collectively, "Studies"**) of such medical device(s) (each a **"Study Device"**); and

WHEREAS, SPONSOR wishes to engage the Institution to perform one or more Studies involving the Study Device(s), as set forth more fully in various Study-specific statements of work attached to this Agreement; and

WHEREAS, the Institution has appropriate facilities and personnel and the Principal Investigator and Sub-investigators (as defined below) have the qualification, training, knowledge and experience necessary to conduct clinical studies and the research program contemplated by this Agreement, which are of mutual interest to SPONSOR and Institution.

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:

1 **Nature of Agreement**. This Agreement establishes the general terms and conditions under which Institution may participate in Studies sponsored by the SPONSOR. For each Study, the parties will enter into a statement of work that sets forth the specific terms and conditions for such Study (a **"SOW"**). Each SOW shall be substantially in the form attached hereto as Exhibit A, and shall at a minimum identify the Study, the protocol for the Study (each, together with any subsequent amendments, the **"Protocol"**), the applicable principal investigator for the conduct of the Study at Institution (the **"Principal Investigator"**), and the budget and payment terms for the Study (the **"Study Budget"**). A SOW may further set forth any additional terms or information specific to the Study that the parties deem to be appropriate. The terms of this Agreement, together with the terms of the applicable SOW, will govern the conduct of each Study. In the event of any conflict between the terms of this Agreement and the terms of a SOW, the terms of this Agreement will control unless the SOW expressly states that the terms of the SOW supersede those in this Agreement for a specific Study. This Agreement shall not apply to a Study, and Institution shall not be obligated to participate in such Study, unless and until an SOW is executed by an authorized representative of each party and acknowledged by the applicable Principal Investigator.

2 Scope of Work.

2.1 **Conduct of the Study**. The Institution, through the applicable Principal Investigator and Sub-investigators, shall conduct each Study in accordance with this Agreement, the applicable SOW, the applicable Protocol, and the applicable investigator's brochure for the Protocol (the **"Investigator's Brochure"**), as each may be amended, and all applicable laws, rules, regulations and guidelines, as adopted into law relating to the conduct of clinical investigations, good clinical practice (GCP) principles, generally accepted medical practice, and applicable export control rules and regulations (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. SPONSOR will use reasonable efforts to perform its applicable obligations in connection with each Study including, but not limited to, monitoring visits.

3 The Principal Investigator and Sub-investigators. The Principal Investigator and Sub-investigators are employees of Institution (or its affiliate physician organization), are otherwise affiliated with Institution, are under contract with the Institution, or are members of the Institution's medical staff. The Principal Investigator will be identified in the applicable SOW. The Principal Investigator is the lead researcher at the Institution responsible for the Study. The Principal Investigator represents and certifies that he or she has read and understands the Protocol and the Investigator's Brochure. The Principal Investigator must read, sign and acknowledge this Agreement via the applicable SOW. Institution may appoint one or more physicians (each a **"Sub-investigator"**) to participate in the performance of the Study under the supervision of the Principal Investigator. During the Study, the Institution shall promptly notify SPONSOR in writing at such time as it becomes aware that the Principal Investigator plans to leave the Institution or shall be unable or unwilling to complete the Study. If the Institution and SPONSOR are unable to agree on an acceptable substitute investigator within thirty (30) business days following such notice, SPONSOR or Institution may terminate the applicable SOW pursuant to Section 22.

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

4.1 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;

4.2 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;

4.3 to the best of Institution's knowledge, neither the Institution, nor the Principal Investigator, nor any other person who assists in performing the Study at Institution is presently 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 interferes with the performance of the Study or that might impair the acceptance of the resulting data by the U.S. Food and Drug Administration (**"FDA"**) or that creates a conflict of interest;

4.4 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 during the term of the Study or within five (5) years thereafter; and

4.5 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**").

4.6 SPONSOR represents and certifies that Institution and 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.

4.7 the Principal Investigator shall supervise all testing of the Study Device at all times during the course of the Study.

4.8 Institution will require each Investigator, including any co-principal investigator, and all-Sub-investigators to sign the Investigator Agreement provided by Sponsor for the purpose of ensuring compliance to applicable regulations.

5 **Facilities**. The Institution and the applicable Principal Investigator shall conduct each Study at the Institution, or such other facilities as SPONSOR and the Institution may agree in writing (each, a **"Facility"**). Such agreement by SPONSOR may be conditioned on SPONSOR requirements communicated at the time a Facility is proposed, which requirements may without limitation include or be based on (i) site visit, (ii) review of site selection questionnaire, (iii) preparation of an Institution ICF that takes into account the Facility's participation, and (iv) Principal Investigator demonstrating that Facility personnel have been adequately trained in the Study procedures. Principal Investigator and Institution remain responsible for compliance with the terms of this Agreement with respect to any Study activities performed at a Facility, and for receiving all funds payable under the SOW and re-distributing such funds to Facility if applicable. Study Data from a Facility will be reported by Investigator in a single consolidated format approved by SPONSOR, unless otherwise instructed by SPONSOR. Provisions of this Agreement that apply to Institution shall also apply to each Facility. The Institution shall make available all personnel, facilities and resources necessary to efficiently and expeditiously accomplish its responsibilities under this Agreement.

6 **Subject Enrollment and Informed Consent**.

6.1 **Subject Enrollment**. The Principal Investigator shall enroll subjects into the Study in accordance with the applicable SOW and the applicable Protocol (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 and the number of Subjects the Institution may enroll in the Study may be extended or shortened at SPONSOR's sole discretion. The Institution acknowledges and agrees that if a Study is part of a study taking place at multiple sites (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.

6.2 **Informed Consent**. The Principal Investigator shall obtain the written informed consent of each Subject prior to any screening or participation in the Study using the Informed Consent Materials (as defined in Section 11.3) and in accordance with Applicable Laws. Institution shall cause each Subject to 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"**). The Informed Consent Materials shall not be modified or amended without prior written approval of the SPONSOR and IRB.

6.3 **Adverse Events**. For each Study, the Institution and Principal Investigator shall notify SPONSOR of any information concerning any device deficiency and 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 the Protocol for each Study with respect to the reporting of adverse Subject experiences. During the term of any relevant SOW SPONSOR agrees to report promptly to Principal Investigator any findings from Study results obtained as part of the Study that could affect the safety or medical care of a Subject or a Subject's willingness to continue participation in the Study, influence the conduct of the Study, or alter the IRB's determination of whether or how the Study should be conducted. After the term of this Agreement, SPONSOR will provide such information about the safety and use of the Study Device as it provides in the normal course of business to respond to a field action, recall, or other action related to the relevant Study Device ("Post-Study Reporting"). Such Post-Study Reporting obligation shall continue for two (2) years following the completion or earlier termination of the Study. In each case, the applicable Principal Investigator and the Institution shall be free to communicate these findings to each Subject and the IRB.

7 Compensation; Fair Market Value.

7.1 **Compensation.** For the services to be rendered pursuant to a SOW, SPONSOR shall pay the Institution in accordance with the applicable Budget. The parties acknowledge that the amounts to be paid by SPONSOR under this Agreement for each individual Study 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 unearned amounts paid by SPONSOR to the Institution for services that have not been performed 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 20 and 22.4, the Institution acknowledges and agrees that for each Study, the payments made by SPONSOR under this Section 6 represent SPONSOR's total obligations under this Agreement and the applicable SOW with respect to such Study, and fully cover the costs of conducting such Study. Unless otherwise provided in the SOW, Study Device is being provided by SPONSOR without charge to Institution, Facility, Subject or other on a Subject's behalf. Institution shall not (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 payor, including Subjects, for any device, equipment, tests, or other Study materials that are provided by SPONSOR at no charge, replaced at no charge, or which are reimbursed by SPONSOR under this Agreement.

7.2 **Fair Market Value**. For each Study, SPONSOR, Institution, and Principal Investigator acknowledge and agree that the compensation and support provided by SPONSOR to Institution and Principal Investigator pursuant to the applicable SOW is intended to represent 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 or such Study Personnel to (a) disclose such Principal Investigator's or Study Personnel's involvement with SPONSOR's Study to such committee to the extent required by Institution's policy; and (b) comply with any procedures set forth by such committee with respect thereto.

8 Financial Disclosure and Reporting.

8.1 **Financial Disclosures by Principal Investigator.** At SPONSOR's written request, the Principal Investigator shall promptly provide to SPONSOR financial disclosure statements in compliance with 21 C.F.R. Part 54, in the form consistent with regulatory requirements as 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 relevant changes to such financial information.

8.2 **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 Payments 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 agrees to keep complete and accurate records, consistent with applicable law and Institution policy, regarding all payments and other transfers of value made in connection with each Study performed pursuant to this Agreement. To the extent not already available to the SPONSOR, Institution 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 upon request. INSTITUTION agrees that SPONSOR may disclose certain information relating to such payments or transfers of value provided to covered recipients as required by law, and acknowledges that such information may become public record.

9 Study Device. The Study Device shall only be used as described in the applicable Protocol and in compliance with Applicable Laws, including those pertaining to Investigational Device Exemptions. The parties acknowledge that the Study Device has not been cleared or approved by the FDA for the indication under investigation in the Study. SPONSOR is the regulatory sponsor for the Study and agrees that it has complied with all applicable laws and regulations, including filing of any required Investigational Device Exemption. The Institution shall maintain complete and accurate records relating to the storage, inventory, and disposition of the Study Device supplied to the Institution, as set forth in Section 11.1.

10 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 THE

APPLICABLE PROTOCOL WILL NOT INFRINGE THE RIGHTS, PATENT OR OTHERWISE, OF ANY THIRD PARTY.

11 Records; Reports; and Regulatory Assistance.

11.1 **Study Documentation**. For each Study, 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 as applicable, and in full compliance with the applicable 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 applicable 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. Study Documentation shall not include Subjects' medical records and other original source documents. 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 reasonable timelines provided by SPONSOR. For studies using web based electronic data capture technology (**"EDC"**), data will be entered in the EDC system at the Institution. 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 11.2). The CRF instructions will also provide the Institution 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 Institution at SPONSOR's reasonable expense. 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 at SPONSOR's reasonable expense. The Principal Investigator's electronic signature on such relevant medical record shall be the legally binding equivalent to a handwritten signature. If medical records of Subjects are held in a computerized medical record system, such system must be in full compliance with the applicable FDA rules on electronic records and signatures. In addition, and if applicable, Institution agrees to keep and maintain such records on the services provided as may be required by fiscal intermediaries, federal, state, or local governmental agencies, accreditation agencies, or other parties.

Pursuant to Section 1395x (v) (1) (I) of Title 42 of the United States Code with respect to any services furnished under the terms of this Agreement, if the value or cost of which is Ten Thousand and No/100 Dollars ($10,000.00) or more over a twelve (12) month period, until the expiration of four (4) years after termination of this Agreement, both parties shall make available, upon written request to the Secretary of the United States Department of Health and Human Services, or upon request by the Comptroller General of the United States General Accounting Office, or any of their duly authorized representatives, a copy of this Agreement and such books, documents, and records as are necessary to certify the nature and extent of the costs of the services provided by Institution employee(s) under this Agreement.

11.2 **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 web=based data capture

(WBDC) system) (collectively, **"CRFs")** completed for each Subject participating in the Study and such other reports as and when required by the applicable Protocol or Applicable Laws. The Institution shall provide the final CRFs required by the Study as set forth in the applicable SOW or such later date as SPONSOR may reasonably require.

11.3 **Institutional Review Board**. Institution represents that the authorized IRB of Institution is registered in accordance with Applicable Laws, and that such registration will be maintained as current throughout the term of this Agreement and each SOW. For each Study, 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 and review the Study during the term of the applicable Study in accordance with Applicable Laws and in any event at least once per year during the term, and shall provide to SPONSOR documentation of the IRB's continuing review contemporaneously therewith. Institution and Principal Investigator must notify SPONSOR in writing within immediately if IRB approval is withdrawn.

11.4 **Regulatory Assistance**. At the request and expense of SPONSOR, the Institution and the Principal Investigator shall: (a) provide reasonable assistance to SPONSOR in the preparation and submission of investigational device exemption applications for the Study Device(s), device premarket notification (510(k)) submissions, premarket approval applications (PMA) for the Study Device(s), any other premarket or marketing applications relating to a Study or the Study Device(s), and any amendments or supplements to the foregoing; (b) reasonably assist SPONSOR in preparing for meetings with the FDA and other regulatory or governmental authorities regarding such applications and the associated approvals; and (c) provide such other reasonable assistance for a reasonable time period as SPONSOR may request in connection with regulatory matters relating to a Study or the Study Device(s).

11.5 **Record Retention**: Institution shall retain Study records for fifteen (15) years following the completion or earlier termination of the Study. At the conclusion of the above-described retention period, Institution shall notify SPONSOR in writing no less than 30 days prior to the expiration of such retention period and will provide the opportunity for: (1) Sponsor to recover the documents (at Sponsor's expense) or, (2) Institution may destroy the records in accordance with Institution's policies; provided, that if SPONSOR requests that Institution continue to retain such records beyond the conclusion of such retention period, then Institution shall continue to retain the records, at SPONSOR's reasonable expense.

12 **Audit, Monitor and Review**. For each Study, SPONSOR or its authorized representatives shall have the right, upon advance written notice, and at mutually agreeable times during regular business hours, to: (a) audit Institution and all Facilities used in performance of the Study, up to twice per year in the absence of a reasonable for-cause determination by SPONSOR in which case additional audits may be conducted; (b) monitor the conduct of the Study; (c) review, copy and audit all Study Documentation, Source Documents (as defined below), any other nonfinancial books, records, data and Work Product (as defined in Section 15.4) relating to the Study, and all required licenses, certificates and accreditation; (d) study, inspect and test all Study Devices after explant if such devices were not otherwise returned to SPONSOR; and (e) interview the Principal Investigator and other persons who assisted in performing the Study. Subjects' medical records shall be made available to SPONSOR in accordance with the terms of the informed consent form and HIPAA authorization signed by Subjects. Institution Information (as defined in Section 16.4) obtained or reviewed by SPONSOR or its authorized

representatives in the course of the audit is subject to the confidentiality obligations set forth in Section 16. For clarity, unless otherwise specified in an SOW, Institution shall not be required to provide to SPONSOR economic data such as UB-04 forms. SPONSOR acknowledges and Institution represents that Institution maintains reasonable standard premises rules relating to confidentiality, safety, and security that are generally applicable to all persons at Institution Facilities. SPONSOR shall communicate any material findings to Institution and Principal Investigator in an exit meeting and in writing within ten (10) business days after completion of an audit. If SPONSOR intends to disclose (report) any adverse findings about Institution or Principal Investigator to any governmental or regulatory authority, or use audit findings as a basis for termination of an SOW or this Agreement, it shall provide Institution with a copy of such audit report, and a copy of any of the information SPONSOR intends to provide to any governmental or regulatory authority, prior to submission thereof, unless SPONSOR is precluded from doing so by law. In such case, SPONSOR shall provide Institution with the report and all such information as soon as SPONSOR is permitted by law to do so.

13 **Changes to the Protocol**. No change in a Protocol shall be made by the Institution or the Principal Investigator without prior approval of SPONSOR and the IRB. Notwithstanding the foregoing, subject to any Applicable Laws relating to the safety of Subjects that may require a deviation from the Protocol, 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 written notice to the Institution, and Institution will act promptly to implement such changes once Institution's IRB has approved such changes; provided, however, that, if the changes materially increase the cost of performance of the Study by the Institution, SPONSOR and Institution will work together to amend the Study Budget or the Institution may terminate this Agreement pursuant to Section 22. Notwithstanding the foregoing, Institution reserves the right to terminate this Agreement or any applicable SOW in the event that changes to the Protocol, in its sole discretion, materially change the terms and conditions of this Agreement or separate SOW.

14 **Regulatory Inspections**. If any governmental or regulatory authority (a) contacts the Institution or the Principal Investigator with respect to a Study, (b) conducts, or gives notice of its intent to conduct, an inspection at any Facility in connection with a Study, or (c) takes, or gives notice of its intent to take, any other regulatory action that is known to Institution and that could reasonably be expected to impact any data or clinical activity under a Study, then the Institution shall notify SPONSOR promptly after such contact or notice to the extent permitted by Applicable Laws and the instructions of the applicable governmental or regulatory authority provided, however, SPONSOR may provide support only and may not in any manner manage or direct such inspection or regulatory action. SPONSOR shall have the right to be present on-site during any such inspection or regulatory action with respect to a Study, to the extent permitted by Applicable Laws and the instructions of the applicable governmental or regulatory authority. The Institution shall provide SPONSOR with copies of all pertinent information and documentation issued by any governmental or regulatory authority and any proposed response. If permitted by Institution's regulatory support staff/department, SPONSOR shall have the right in advance to review and comment on any responses that pertain to the Study. For avoidance of doubt, no right of editorial control by SPONSOR is provided or implied hereunder. No such response shall contain any false or misleading information with respect to the Study, the Study Device or SPONSOR.

15 Ownership of Materials, Intellectual Property and Work Product.

15.1 **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 a Study, unless specifically agreed to otherwise by SPONSOR in writing. If SPONSOR provides Institution with SPONSOR software or computers, it shall be addressed in the SOW, and SPONSOR shall be required to comply with institutional security policy, as applicable. To the extent SPONSOR supplies computers for use in connection with a Study, Institution agrees that no software may be installed unless there is agreement in writing that such software is required to conduct the Study ("Information Security Agreement"). Information Security Agreement shall describe Institution security requirements for the SPONSOR supplied computers. Institution agrees to keep all Materials free from liens or encumbrances. The Institution shall: (a) use the Materials only for the purposes described in the applicable Protocol(s) or such other purposes as SPONSOR may approve in writing, (b) restrict access to and use of the Materials to the applicable Principal Investigator and other personnel for whom such access and use is required to conduct the applicable Study(ies), 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 the applicable SOW, or (iii) as otherwise reasonably requested in writing by SPONSOR.

15.2 **Retained Rights**. Each party to this Agreement shall retain all Rights in any patent, patent application, trade secret, know-how, trademarks, copyrights, and other intellectual property that was owned by such party prior to the Effective Date of this Agreement or arising outside of any Study 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. Neither Institution nor SPONSOR shall adopt, use or register any words, phrases or symbols, which are identical to or confusingly similar to any of the party's trademarks.

15.3 **Inventions.** Any invention, innovation, discovery, improvement, design, apparatus, practice, process or method (whether or not patentable or copyrightable) ("**Intellectual Property**"), made, perfected, devised, conceived or reduced to practice, by Institution, Principal Investigator, or Study Personnel as a result of the use of the Study Device or any Materials or the performance of the Study and necessarily incorporating or necessarily arising from using the Study Device, Protocol, or Confidential Information ("**SPONSOR Intellectual Property**") shall be promptly disclosed, in writing, to the SPONSOR and shall be the sole property of the SPONSOR., Each of Institution, Principal Investigator, and Study Personnel hereby assigns to SPONSOR all Rights in and to said SPONSOR Intellectual Property. Title to any Intellectual Property made, perfected, devised, conceived or reduced to practice, by Institution, Principal Investigator, or Study Personnel in the performance of the Study that do not constitute SPONSOR Intellectual Property shall constitute "**Other Inventions**", and shall be determined in accordance with U.S. Patent Law. For each Other Invention developed (a) solely by Institution and/or Investigator, or (b) jointly by Institution and/or Investigator and Sponsor, Sponsor shall have the option to negotiate for an exclusive, royalty-bearing license to all rights in such Other Invention. This option must be exercised within the later of one hundred eighty (180) days of Sponsor's receipt of written notice of each such Other Invention, or one hundred eighty (180) days after the Expiration Date ("**Option Period**"). If Sponsor and the Institution fail to reach a mutually agreeable license agreement within 90 days from the date on which the option is exercised, the Institution shall have no further obligation to Sponsor, except that if the parties are unable to agree on licensing terms, then for a period of one year thereafter, Institution shall not license the Other Invention to a third party on

financial terms more favorable to the licensee than those last offered to Sponsor without first giving Sponsor an opportunity to license the Other Invention on those more favorable terms. Institution and the applicable Principal Investigator shall, upon the SPONSOR's request and at the SPONSOR's expense, execute such documents and take such other actions as the SPONSOR deems reasonably necessary or appropriate to obtain patent or other proprietary protection of SPONSOR Intellectual Property.

15.4 **Work Product**. For each Study, 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 Data and 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 arising directly out of the Study and in the course of the performance of the Study under the applicable SOW in accordance with the applicable Protocol (collectively, **"Work Product"**). Work Product shall not include Institution's financial records, internal administrative and regulatory records, Subjects' medical records, other original source documents, publications or presentations authored by Institution's personnel in accordance with Section 18.2. 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.

15.5 **Assistance.** The Institution shall, and shall cause the applicable Principal Investigator and any inventor to, where applicable and consistent with the requirements of this Agreement at SPONSOR's sole expense and adhering to applicable law: (a) execute all documents and perform all acts reasonably deemed necessary by SPONSOR to evidence SPONSOR's ownership of any SPONSOR Intellectual Property and Work Product (including the making of any biological deposits) and (b) use good faith efforts to assist SPONSOR in preparing, prosecuting, obtaining, registering, maintaining, defending and enforcing, at SPONSOR's sole expense, 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 SPONSOR Intellectual Property and the Work Product in any and all countries as may be determined by SPONSOR.

15.6 **Attorney-In-Fact.** The parties agree that any designation of SPONSOR as attorney-in-fact or as having any other capacity to act on behalf of Institution or Principal Investigator with respect to a Study will be addressed in the applicable SOW.

15.7 **Government-Funded Activities**. The parties hereto agree that all activities under this Agreement and the SOWs entered into hereunder (**"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 Intellectual Property 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, the applicable Principal Investigator and any other inventor shall take all actions necessary to retain title to any

Intellectual Property made under this Agreement, including those required by 37 C.F.R. §§ 401.14(c)(1), (2) and (3). In the event that any Intellectual Property 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 SPONSOR Intellectual Property or Work Product under Sections 15.1 through 15.6, the Institution and the applicable Principal Investigator shall and do hereby, and the Institution shall cause each other inventor to: (a) seek 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 SPONSOR Intellectual Property or Work Product, subject to the right of the U.S. Government to retain an irrevocable, royalty-free right to use SPONSOR Intellectual Property or Work Product throughout the U.S. Government.

15.8 **Medical Records.** Institution and/or the medical provider, as applicable, shall retain ownership of its patient medical records, investigator lab notebooks, and other original source documents (collectively, the "Source Documents"), and may use such records Source Documents, as it deems reasonable and appropriate in accordance with Applicable Laws.

16 Confidential Information.

16.1 **Definition**. SPONSOR shall not disclose Confidential Information to Institution unless it is necessary to the Study. For purposes of this Agreement, **"Confidential Information"** means any information of SPONSOR, whether of a technical, business or other nature, including the terms of this Agreement and any SOW (subject to Institution's internal and/or legal reporting requirements), information that relates to SPONSOR's products, the Study Device, promotional material, developments, proprietary rights or business affairs, together with any SPONSOR Intellectual Property, 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 this Agreement or in connection with any Study hereunder or in contemplation of any SOW. All Confidential Information disclosed by SPONSOR shall be marked or identified as confidential, provided that information which is not marked or identified but that a reasonable person under the same or similar circumstances would understand to be confidential in nature shall also be considered Confidential Information. For purposes of this Agreement the definition of Confidential Information does not include trade secrets. If SPONSOR intends to disclose a trade secret, it will advise Institution in advance and the parties will agree in writing as to the proper handling of that information. In the event SPONSOR notifies Institution in writing that SPONSOR trade secrets have been inadvertently disclosed, Institution agrees to immediately destroy or return such trade secret information. This Section 16 is subject to the Institution and the Principal Investigator's publication rights as set forth in Section 18. Confidential Information does not include any information that:

16.1.1 the Institution or the Principal Investigator can demonstrate through written documentation was known prior to the date of this Agreement and was not subject to any confidentiality restrictions;

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

16.1.3 is or becomes publicly available through no act or violation of any obligation of the Institution or the Principal Investigator under this Agreement; or

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

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

16.2 **Non-Disclosure.** Subject only to Section 16.4 and unless otherwise specified in an SOW, for a period of five (5) years after the expiration or termination of the Study, the Institution and the applicable Principal Investigator shall not, without SPONSOR's prior written consent or as may be permitted by this Agreement or the applicable SOW, disclose to any third party any Confidential Information, and shall use such Confidential Information solely for purposes of performing its obligations under this Agreement and the applicable SOW. The Institution shall restrict the dissemination of Confidential Information to only those persons within the Institution and Facilities who have a need to know, and shall ensure that they are aware of the obligation of confidentiality required by this Agreement, provided that all such personnel are subject to Institutional policies of confidentiality similar to those herein. The Institution and the applicable Principal Investigator shall use at least the same care and discretion in maintaining the confidentiality of the Confidential Information as each uses with its confidential information of a similar nature. The Institution or the applicable 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 applicable Principal Investigator shall promptly return to SPONSOR all Confidential Information at SPONSOR's reasonable expense; provided, however, that Institution may retain one (1) copy of Confidential Information for its legal, regulatory, disaster preparedness (such as automated backups) and compliance purposes.

16.3 **Exceptions to Non-Disclosure**. Notwithstanding Sections 16.2 and 16.3, 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 and to the extent permitted by law, shall use reasonable efforts to promptly notify SPONSOR in writing prior to making the required disclosure. If such disclosure is required pursuant to a lawful subpoena or judicial or government request or 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 use reasonable efforts under the circumstances to 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 information relating to the Study to those individuals who have a need to know to 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, to the extent practicable, and promptly after it has made such a disclosure.

16.4 **Institution Information.** In the course of a Study, SPONSOR may be provided with or have access to information of Institution, Principal Investigator, and/or Study Personnel, including, without limitation, information relating to scientific data, business operations, procedures, technical information, medical records, financial information and personal information, which shall remain the property of Institution (collectively, **"Institution Information"**). All Institution Information shall be marked as confidential, provided that information which is not marked but that a reasonable person under the same or similar circumstances would understand to be confidential in nature shall also be considered Institution Information. SPONSOR will hold all Institution Information in confidence in accordance with the same terms that oblige Institution as set forth above in Sections 16.1, 16.2, and 16.3. SPONSOR will use the Institution Information solely for the purpose of the performance of this Agreement. Institution and Principal Investigator shall not disclose confidential Institution Information to Sponsor unless it is necessary to the Study.

17 Privacy and HIPAA.

17.1 **Covered Entities**. For each Study, the Institution and the applicable Principal Investigator each represent, certify and covenant that they may be or have affiliates that are "Covered Entities" under the provisions of the Health Insurance Portability and Accountability Act of 1996 and any regulations and official guidance promulgated thereunder (**"HIPAA"**). Institution and the Principal Investigator shall handle all Study Documentation (including Subjects' medical records) in accordance with all applicable 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.

17.2 **SPONSOR Not Covered By HIPAA**. SPONSOR represents, warrants and covenants, and the Institution and the Principal Investigator acknowledge such representation, warranty and covenant, that, except as otherwise required by Applicable Law, 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. Nevertheless, SPONSOR agrees to fully cooperate and to not interfere with the efforts of Institution to maintain compliance with HIPAA and other applicable laws and regulations concerning the use, disclosure, and maintenance of patient medical records and other health information. SPONSOR agrees to abide by the terms of the informed consent form and HIPAA authorization signed by Subjects, and to comply with all federal and state health information confidentiality laws and regulations applicable to it. If SPONSOR gains access to any Subject medical records or protected health information that is not covered by an informed consent form or HIPAA authorization, SPONSOR shall hold such information in the strictest confidence, shall not remove records containing such information from the Institution and, if inadvertently removed, shall immediately return any records containing such information to the Institution.

18 Publication and Use of Study Results.

18.1 **Study Data**. For each Study, the Institution and the applicable Principal Investigator acknowledge and agree that the data collected during the Study ("Study Data"), except as otherwise provided in Section 15.8, is owned by SPONSOR. SPONSOR may use all Study Data collected during the Study for any and all purposes at the sole discretion of SPONSOR, provided

it is consistent with Applicable Laws and regulations, this Agreement and the informed consent form signed by the Subject. Study Data is confidential, and Institution agrees that premature disclosures of the data may be misleading. If the Study is a Multi-Center Study, then 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 applicable 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"**). Further, for a Multi-Center Study, the SPONSOR, or its designee, shall have the right to coordinate one or more publications of the Multi-Center 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 applicable Principal Investigator at the completion or earlier termination of the Study. Any access by Institution and/or its Principal Investigator to the Study Data from all Study sites for Institution and/or Principal Investigator will be addressed in the Study SOW.

18.2 **Publication and Use of Study Data**. Unless otherwise specified in the applicable SOW, the Institution may use the Site Data (and, for a Multi-Center Study, the Multi-Center Study Results) for the limited purpose of its own research, patient care, publications, and academic analysis, provided that, subject to Section 18.1 and 18.3, neither the Institution nor the Principal Investigator shall make any publication or presentation with respect to the Study and, if applicable, the Multi-Center Study, or the respective results (unless otherwise stated in an applicable SOW) until the earlier of (i) eighteen (18) months after the completion, or earlier termination of the Study at all sites, in the case of a Multi-Center Study, or twelve (12) months after the completion, or earlier termination, of the Study in the case of a single-center Study, (ii) in the case of a Multi-Center Study, the first publication of the Multi-Center Study Results, or (iii) SPONSOR's confirmation that there will be no publication of the Multi-Center Study Results. In no event shall the Institution or the Principal Investigator publish, cause to be published or make any presentation disclosing the raw Site Data or, if applicable, any other Multi-Center Study Data (as distinguished from results of analyses of the Site Data and, if applicable, the Multi-Center Study Results), unless required by the journal editor or publisher for the purpose of supporting the analysis and conclusions made in such publication or unless authorized by the SPONSOR in writing (such authorization not to be unreasonably withheld or delayed). Neither Institution nor Principal Investigator will make any publication or presentation that is false or misleading or is for commercial purposes.

18.3 **SPONSOR Review**. Unless otherwise specified in the applicable SOW, the Institution and the Principal Investigator shall submit a copy of any proposed manuscript, abstract, presentation or other document with respect to a Study, including any Multi-Center Publication of which the Principal Investigator is an author, to SPONSOR for review and comment at least forty-five (45) days prior to its submission for publication or presentation. Institution and/or Principal Investigator shall reasonably consider SPONSOR's comments on the proposed publication or presentation and shall remove any Confidential Information and correct any inaccurate technical information that may be identified by the SPONSOR in writing. Notwithstanding the foregoing, any analyses performed by the Principal Investigator using the Site Data (or, in the case of a Multi-Center Study, any Multi-Center Study Analyses) or that have been disclosed in a publication or presentation authorized pursuant to this Section 18 or pursuant to another clinical study agreement under the Study, shall not be deemed Confidential Information for purposes of this Section 18. If requested in writing by SPONSOR, the Institution and the

Principal Investigator shall withhold material from submission for publication or presentation for an additional sixty (60) days to allow for the filing of a patent application or the taking of other measures to establish and preserve SPONSOR's proprietary rights. Notwithstanding the foregoing, in no event shall Institution or Principal Investigator be required to delay a submission for publication or presentation for more than one hundred twenty (120) days after first submission of a complete publication or presentation to SPONSOR for review. Institution agrees to submit such publication in form that allows SPONSOR to conduct a review sufficient to remove any Confidential Information, correct any inaccurate technical information, and determine if delay is necessary to pursue submission of a patent application. Unless otherwise agreed to in the body of an SOW, to the extent that any provision of this Section 18 may be inconsistent in any respect with any statements about publication policy set forth in a Protocol, the provisions of this Section 18 shall control.

18.4 **Authorship and Final Contents**. Subject to the foregoing, the authorship and final contents, including scientific conclusions and professional judgments, of any paper submitted about a Study (or, if applicable, a Multi-Center Study) by the Principal Investigator shall be determined by the Principal Investigator in accordance with the publication guidelines of the International Committee of Medical Journal Editors.

18.5 **License to SPONSOR**. The Institution and the Principal Investigator agree that, if either publishes the results of a Study or a Multi-Center 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, if any. SPONSOR also shall have the right to publish independently the results of each Study and each Multi-Center Study.

18.6 **Clinical Trial Registries and Clinical Results Databases**. SPONSOR is responsible for, and agrees to, register the Study and post the results information in accordance with the requirements of the Public Service Act, 42 U.S.C. 282(j)(1)(A), if applicable, as determined by SPONSOR. Institution agrees that it will not register the Study.

19 Use of Name; Advertising.

19.1 **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 any 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 in: (i) non-public Study-related communications (including Study newsletters shared with other sites), (ii) internal reports, (iii) clinical trial registries, (iv) communications with regulatory authorities, (v) publications and presentations, (vi) public disclosures required by law, regulation, or regulatory authorities, and (vii) any clinical trial website and similar public notifications of clinical trials offered by Institution. The Institution may use the name of SPONSOR, the title of the Study and other information as consistent with information provided about a Study in public clinical trial registries for: (i) C.V.s, (ii) internal reports, (iii) publications and presentations made pursuant to Section 18, (iv) grant applications to government and other funding sources, (v) required government reports and filings, (vi) Institution's clinical trials website and similar public notifications of clinical trials offered by Institution; and (vii) conflict of interest disclosures.

19.2 **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 Subjects, regarding any Study without the prior written permission of SPONSOR and the review and approval of the IRB.

20 Indemnification, Insurance and Limitation of Liability.

20.1 **Indemnification by SPONSOR.** SPONSOR will indemnify, defend and hold harmless the Institution, the Facility where Institution conducts the Study, the IRB (solely with respect to its role in the approval and regulatory oversight of the Study), and their respective subsidiaries, affiliated hospitals, trustees, directors, officers, faculty, agents, employees, students, the Principal Investigator and any Sub-investigator and their respective employers (individually an **"Institutional Indemnified Party"** and collectively, the **"Institutional Indemnified Parties"**) from and against any and all third party actions, suits, claims, proceedings, investigations, demands, costs and expenses (including reasonable attorney fees incurred prior to engagement of counsel for the Institutional Indemnified Party by SPONSOR Indemnifying Party), judgments, liabilities, losses, personal injuries (including death), or other damages (collectively, **"Losses"**), of all types whatsoever, that have arisen from or are related to the (a) use of the applicable Study Device(s) in accordance with the applicable Protocol or procedures that the Subject would not have undergone but for participation in the Study (b) SPONSOR's negligence or misconduct, (c) breach of this Agreement, (d) SPONSOR's failure to comply with Applicable Law, or (e) SPONSOR's use or commercialization of the Study Results or Intellectual Property. The SPONSOR's obligation to indemnify, defend and hold harmless an Institutional Indemnified Party will be reduced to the extent that any Losses are adjudicated to have been directly caused by: (i) a material failure by such Institutional Indemnified Party to comply with the applicable Protocol, allowing for deviations for Subject safety, and/or with state or federal statutes or regulations, including FDA regulations; or (ii) the negligence or misconduct of such Institutional Indemnified Party, provided that complying with the applicable Protocol, SPONSOR's instructions, or the terms of this Agreement or the applicable SOW shall not be considered negligence for purposes of this exception.

20.2 **Indemnification by Institution**. Subject to the limits and without waiving any immunities provided under applicable law (including constitutional provisions, statutes and case law) regarding the status, powers and authority of the Institution or the Institution's principal(s), Institution shall indemnify, hold harmless and defend SPONSOR, its directors, officers, employees and agents, (individually a **"SPONSOR Indemnified Parties"** and collectively, the **"SPONSOR Indemnified Parties"**) from and against only Losses to the extent directly attributable to Institution's negligence or misconduct in its conduct of the Study. Notwithstanding the above, Institution shall have no obligation to indemnify SPONSOR for any other Losses (including, but not limited to, product liability claims).

20.3 **Reimbursement of Medical Expenses.** Institution will offer or will coordinate medical care to Subjects who suffer an adverse reaction, illness, or injury during a Study. For each Study, SPONSOR will reimburse Institution or other medical provider at rates that constitute fair market value for industry sponsored studies, for the reasonable and necessary, actually incurred costs of providing such medical diagnosis and treatment of any adverse reaction, illness or injury directly arising from the use of the applicable Study Device(s) in accordance with the applicable Protocol or procedures that the Subject would not have undergone but for participation in the Study. Notwithstanding the foregoing, SPONSOR's obligation to reimburse Institution will be reduced to the extent that such adverse reaction, illness or injury is attributable to: (i) the negligence or misconduct of Institution, the applicable Principal

Investigator, or their respective employees and agents; (ii) if applicable, a known risk of an FDA approved treatment or device of the type being studied; (iii) failure to adhere to the applicable Protocol (it being understood, however, that emergency medical care shall not be deemed a violation of the Protocol), other non-conflicting written instructions provided by SPONSOR, or Applicable Laws by Institution, the applicable Principal Investigator, or their respective employees and agents; or (iv) the natural progression of a pre-existing medical condition or underlying disease of the Subject. For purposes of this Section causation of adverse reactions, illness and injury, and whether the exception set forth in Section 20.3(iii) applies shall be determined in the reasonable medical judgement of the Principal Investigator after consultation with SPONSOR and good faith consideration of all data presented by SPONSOR related to causation. SPONSOR's agreement to pay Institution under this Section 20.3 is being provided as reasonable consideration for Subjects' willingness to participate in a 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.

20.4 **Indemnification Procedures.**

20.4.1 Conditions of Indemnity. The party seeking indemnification pursuant to this Section 20 (each an **"Indemnitee"**) will promptly notify the other party (each an **"Indemnitor"**) of any indemnifiable action, suit or claim (**"Claim"**) of which it becomes aware, and each Indemnitee will cooperate with the Indemnitor and its insurance carrier in the defense of any such Claim. The Indemnitor agrees, at its sole expense, to diligently defend against any such Claim against any Indemnitee whether or not such Claim is rightfully brought or filed. With respect to any Claim as to which the Indemnitor has irrevocably acknowledged a duty to indemnify the Indemnitees, the Indemnitor will be entitled to conduct and direct defense of the Indemnitees against such Claim using qualified attorneys of Indemnitor's own selection, but Indemnitor will consult with the Indemnitees on litigation strategy and any proposed settlements. The Indemnitor will not enter into a settlement agreement of any such Claim without the Indemnitee's prior written approval unless the settlement agreement: (i) includes a full and unconditional release of each Indemnitee and (ii) has no finding or admission of any violation or wrongdoing by any Indemnitee. At the individual option of an Indemnitee, such Indemnitee may defend itself at its own expense.

20.4.2 No Acknowledgement of Liability. The assumption of the defense of a Claim by the Indemnitor shall not be construed as an acknowledgment that the Indemnitor is liable to indemnify any Indemnitee in respect of the Claim, nor shall it constitute a waiver by the Indemnitor of any defenses it may assert against the Indemnitee's claim for indemnification.

20.5 **Insurance**.

20.5.1 Insurance Coverage. Institution (on its own behalf and on behalf of the Principal Investigator) and SPONSOR shall each maintain, at the minimum the following insurance coverages:

(i) errors and omissions liability insurance coverage of not less than one million dollars ($1,000,000) per claim and three million dollars ($3,000,000) in the aggregate; and

(ii) general liability insurance coverage of not less than two million dollars ($2,000,000) per claim and four million dollars ($4,000,000) in the aggregate.

(iii) cyber/privacy and security liability insurance of not less than three million dollars ($3,000,000) per claim and three million dollars ($3,000,000) annual aggregate.

20.5.2 Policy. The coverage shall remain in place throughout the term of the applicable Study and, if a policy is a claims-made policy, of an additional three (3) years after completion of the Study. For clarity, the foregoing insurance requirements shall not in any way limit a party's liability with respect to its indemnification or other obligations under this Agreement

20.5.3 Certification**.** Each party may satisfy some or all of its insurance obligations under this Agreement through a reasonably managed program of self-insurance; provided that the financial strength of Sponsor and/or Institution, as applicable, can reasonably support the financial obligation. Each party shall, at the other party's written request, have its insurance carrier or carriers, or with respect to a self-insurance program have an appropriate officer of such party, furnish to the other party certificates evidencing that all insurance coverages and limits required under this Agreement is in force, such certificate to indicate any deductible and any self-insured retention. Each party shall promptly provide the other party with written notice of any cancellation, non-renewal, and expiration or material modification of any required insurance or self-insurance.

20.5.4 Additional Coverages and Terms. Additional coverages and/or terms related to coverage required under this Agreement may be reflected in an SOW.

20.6 **Limitation of Liability. EXCEPT FOR EACH PARTY'S, INDEMNITY AND DEFENSE OBLIGATIONS PURSUANT TO SECTION 20 FOR CLAIMS ASSERTED BY THIRD PARTIES OR DAMAGES ARISING FROM EITHER PARTY'S GROSS NEGLIGENCE, WILLFULL MISCONDUCT OR FRAUDULENT ACTS, 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, AN SOW, A PROTOCOL OR A 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. LOSSES ATTRIBUTABLE TO BREACHES OF SECTIONS 15 AND 16 ARE NOT SPECIAL INCIDENTAL CONSEQUENTIAL OR INDIRECT DAMAGES WITHIN THE MEANING OF THIS SECTION.**

21 Term. This Agreement shall be effective as of the Effective Date and shall continue until the earlier of (i) the completion of the final Study conducted under a SOW hereunder, or (ii) the date that this Agreement is terminated in accordance with Section 22.

22 Termination.

22.1 **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, withdrawal of approval to continue the Study by the IRB or FDA, or as otherwise required by Applicable Laws. Further, SPONSOR may immediately terminate or suspend any Study if such Study is terminated or suspended at all other Study sites. SPONSOR or Institution may terminate the Institution's participation in a Study, in its sole discretion, without cause, on thirty (30) days prior written notice to the other party. SPONSOR or the

Institution may terminate a SOW in the event of material breach by the other of this Agreement or the applicable SOW, 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. Termination of a SOW shall constitute termination of such SOW only, and shall not affect this Agreement or any other SOW.

22.2 **Right to Terminate Agreement**. SPONSOR or Institution may terminate this Agreement, in its sole discretion, without cause, on thirty (30) days prior written notice to the other party. 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. Notwithstanding termination or expiration of this Agreement, any SOW in effect at the time of such termination or expiration shall remain in effect until the obligations of the parties thereunder have been completed or such SOW is terminated according to Section 22.1

22.3 **Transition Upon Termination**. Upon notice of termination of a Study or this Agreement, the Institution shall immediately cease enrollment of Subjects into such Study and shall terminate such 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. 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 9 and the instructions of SPONSOR 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 a Study, the Institution shall immediately cease enrollment of Subjects into such Study. SPONSOR shall reimburse Institution for all reasonable additional and non-cancelable expenses not contemplated by the SOW budget that incurred from such transition, including due to early termination.

22.4 **Payment Owed**. Except in the case of termination of this Agreement as a result of an uncured, material breach of this Agreement by the Institution, upon termination of an SOW, SPONSOR shall, upon receipt of applicable invoices and other supporting documentation reasonably satisfactory to SPONSOR: (a) reimburse the Institution for its necessary Study costs and necessary un-cancelable Study costs and expenses incurred in connection with transfer of Subjects pursuant to Section 22.3 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 the applicable Study Budget for work already performed in accordance with the Study. For clarity, the SPONSOR shall pay for all work performed and Study expenses incurred in accordance with the applicable Study Budget until the point of the material breach by Institution.

22.5 **Final Accounting**. Within ninety (90) days after the termination of a Study under this Agreement, the Institution shall deliver to SPONSOR a final accounting of all Subjects participating in such Study and the visits completed in accordance with the applicable Protocol during the term of this Agreement, and all reasonable costs incurred in connection with any transfer or termination of such Study. Within ninety (90) days of delivery or receipt of the final accounting, either the Institution shall refund to SPONSOR any excess amounts paid by SPONSOR for services not yet provided or SPONSOR shall pay any additional amounts owed to the Institution. SPONSOR, consistent with Section 12 above or its designee shall have the right, at mutually-agreeable times during normal business hours for a period of two (2) years

after the payment of any transfer costs to audit the Institution's records with respect to such accounting, if required for SPONSOR's compliance with regulatory reporting requirements.

23 **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.

24 **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(s) or (c) to any direct or indirect affiliate of such assigning party. In the case of assignment of this Agreement, the assigning party shall provide prompt written notice to the other party.

25 **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.

26 **Governing Law**. Intentionally omitted.

27 **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, 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]
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 27. Such notice shall be deemed to have been given as of the date delivered by hand on the second business day (at the place of delivery) after deposit with an internationally recognized overnight delivery service, whichever is the earlier. This Section 27 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.

28 **Survival**. The respective rights and obligations of the parties set forth in Sections 7 (other than the first sentence), 8-12, 14-20, 22, 27 and this Section 29 shall indefinitely survive the expiration or termination of this Agreement to the extent necessary to preserve such rights and obligations.

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

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

31 **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.

32 **Inconsistency**. In the event of any inconsistency between this Agreement or a SOW and a Protocol, the terms of the Protocol shall prevail with respect to matters of medicine, science, the conduct of the Study and the treatment of Subjects in connection therewith; in all other respects, consistent with Section 1, the terms of this Agreement or the applicable SOW shall prevail.

33 **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

34 **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.

35 **Force Majeure**. Neither party shall be liable for any failure to perform as required by an SOW to this Agreement to the extent such failure to perform is due to circumstances reasonably beyond such Party's control, including, without limitation, labor disturbances or labor disputes of any kind, accident, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrence.

36 **Compliance with Laws.** The parties and their respective affiliates, as applicable, will to adhere to the provisions of (i) the United States federal anti-kickback statute (42 U.S.C. 1320a-7(b) and the related safe harbor regulations; (ii) the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. 1395 (n)); (iii) the Foreign Corrupt Practices Act 1977 of the United States of America ("FCPA"); and (iv) any other applicable anti-corruption legislation ((i) through (v) are individually and collectively referred to herein as "Anti-Corruption Legislation"). If any portion of this Agreement or SOW is found, by any court or agency with jurisdiction over the subject matter hereof, not to be in compliance with any Anti-Corruption Legislation, that portion of the Agreement or SOW shall be deemed to be retroactively amended and reformed as necessary to comply with the applicable Anti-Corruption Legislation, and the parties shall cooperate in taking whatever steps are necessary to ensure such compliance.

37 **Rights of Third Parties.** Nothing in this Agreement is intended to confer on any party that is not a Party (or Principal Investigator) to this Agreement any right to enforce any term of this Agreement.

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 :	Title : .....
Date: …….	Date: …….

EXHIBIT A

SAMPLE STATEMENT OF WORK

This Statement of Work (**"SOW"**) is issued pursuant to the EFS Master Clinical Study Agreement (the (**"Agreement"**), dated as of [ ], by and between **[SPONSOR NAME]**, a [ ] corporation, with offices at **[ADDRESS]** (**"SPONSOR"**) and **[INSTITUTION NAME]**, a [ ] corporation with offices at **[ADDRESS]** (**"Institution"**). This SOW is effective as of [ ] (**"SOW Effective Date"**) and incorporates all of the terms and conditions of the Agreement. SPONSOR and Institution may be referred to herein individually as "Party" and collectively as the "Parties".

Any capitalized terms not otherwise defined herein shall have the same meaning ascribed to them in the Agreement.

A. Principal Investigator(s):

Name: _____

Address: _____

_____

_____

Phone: _____

B. Protocol Title and Number:

_____ (the **"Study"**)

A copy of the Protocol is attached hereto as Schedule 1 and incorporated herein by reference.

C. Study Device

_____ inclusive of all delivery systems and accessories (the **"Study Device"**).

D. Study Facilities:

_____

E. Study Budget.

A copy of the Study Budget is attached hereto as Schedule 2 and incorporated herein by reference. Payment as set forth in the Study Budget shall constitute full payment for the performance of the Study.

F. [ADDITIONAL TERMS]

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

[NAME OF SPONSOR]

Signature : .....

Name : .....

Title : .....

Date: ……

[NAME OF INSTITUTION**]**

Signature : .....

Name : .....

Title : .....

Date: ……

PRINCIPAL INVESTIGATOR
(READ AND ACKNOWLEDGED IF AN EMPLOYEE OF INSTITUTION)

Signature : .....

Name : .....

Title : .....

Date: ……

Schedule 1 to Exhibit A

Protocol

Schedule 2 to Exhibit A

Sample Study Budget

[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: [ ]

   2.2 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.

   2.3 Payment Schedule

   SPONSOR agrees to pay according to the following schedule:

   2.3.1 One (1) payment of $[INSERT AMOUNT] for non-refundable administrative study start-up fee.

   2.3.2 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.

   2.3.3 The following items will be submitted by the Institution to SPONSOR as applicable:

2.3.3.1 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.

2.3.3.2 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: _____