**CLINICAL TRIAL AGREEMENT**

The CONFORM Pivotal Trial: An evaluation of the safety and effectiveness of the Conformal Left Atrial Appendage Seal (CLAAS) for Left Atrial Appendage Occlusion

 This CLINICAL TRIAL AGREEMENT (**“Agreement”**) is made effectiveas of the last date of the Parties’ signature to this Agreement(the **“Effective Date”**), and is by and between CONFORMAL MEDICAL, INC., having a business address at 15 Trafalgar Square, Ste. 101, Nashua, NH (“**Conformal**” or **“Sponsor”**) and **[INSTITUTION NAME]**, having a business office at **[ADDRESS]** (**“Institution”**). Sponsor and Institution may be individually referred to as a “Party” or collectively referred to as the “Parties”. Institution employs **[INVESTIGATOR NAME]** MD, (“**Principal Investigator**”).

 **WHEREAS**, Sponsor is engaged in the development of medical device technologies, and in connection therewith intends to conduct a randomized (device-device) Pivotal Trial (**“Study”)** to assess the safety and effectiveness of the Conformal Left Atrial Appendage Seal (“**CLAAS**” or “Study **Device**”) according to the clinical protocol, entitled “CONFORM Pivotal Study: An evaluation of the safety and effectiveness of the Conformal Left Atrial Appendage Seal (CLAAS) for Left Atrial Appendage Occlusion,” as amended from time to time (“**Protocol**“).

 **WHEREAS**, the Study that is the subject of this Agreement is of mutual interest and benefit to the Parties because it furthers instructional and research objectives and may benefit patient care.

 **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**. The terms of this Agreement shall govern the conduct of the Study and the Parties. This Agreement shall not apply to the Study and Institution shall not be obligated to participate in the Study, unless and until it is executed by an authorized representative of each Party and acknowledged by the Principal Investigator.
2. **SCOPE OF WORK**.
	1. **Conduct of the Study**. The Institution, through the Principal Investigator and Sub-investigators, shall conduct the Study in accordance with this Agreement and the Protocol, as each may be amended, and all applicable laws, rules, regulations and guidelines as further detailed in Sec. 8 below (“**Applicable Laws**”) as adopted into law relating to the conduct of clinical investigations, and good clinical practice (“**GCP**”) principles generally accepted medical practice as well as applicable export control rules and regulations. 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 the Study including, but not limited to, monitoring visits.
3. **PERFORMANCE OF THE STUDY**

* 1. **The Principal Investigator**.The Principal Investigator and sub-investigators are employees of Institution (or its affiliate physician organization), are otherwise affiliated with Institution, or are under contract with the Institution or are members of the Institution’s medical staff. 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. The Principal Investigator must read, sign and acknowledge this Agreement. Except in instances of Principal Investigator’s emergency absence, illness or death, Institution and Principal Investigator shall provide Sponsor at least thirty (30) days’ written notice that Principal Investigator is unable or unwilling to continue the Study for any reason. If Principal Investigator becomes unable or unwilling to continue with the Study, Institution shall notify Sponsor and shall seek to find a replacement investigator within thirty (30) days. Sponsor may, at its option, either continue the Study with the substitute principal investigator or terminate the Study. In the event of continuation, the substitute principal investigator shall acknowledge his or her new duties as Principal Investigator and agree to be bound by the terms of this Agreement. Sponsor and Institution shall execute a written amendment acknowledging the substitution. If Sponsor does not approve the substitute principal investigator proposed by Institution or Institution does not have a substitute to propose, then either Party may terminate this Agreement upon thirty (30) days advance written notice to the other Party.
	2. **Sub-Investigators**. The Institution and Principal Investigator may appoint qualified collaborating physicians (“Sub-Investigators”) to participate in the Study (the Principal Investigator and any Sub-Investigators may individually be referred to as “Investigator” and collectively as the “Investigators”). All Sub-Investigators shall work under the supervision of Principal Investigator and must agree to be bound by the same terms and conditions that bind the Principal Investigator under this Agreement by executing Exhibit A to this Agreement.
	3. **Institutional Review Board**. Institution represents that the authorized Institutional Review Board (“**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. Prior to enrolling any research subjects in the Study, Principal Investigator will obtain the written approval of the IRB who will review and approve the terms and conditions of the Study, including the Protocol, the Informed Consent Materials (as defined below), and any subject recruitment materials, if applicable. The Institution shall provide to Sponsor documentation verifying approval by the IRB of (i) the Informed Consent Materials (as defined below), (ii) the Protocol, and (iii) amendments to any of the foregoing. The Institution shall ensure 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 immediately if IRB approval is withdrawn.
	4. **General**. The Investigators will use their professional expertise to conduct the Study according to the terms and conditions of this Agreement and in strict compliance with the Protocol that has been approved by Sponsor and IRB for use in the Study, and any approved amendments and revisions thereto.
	5. **Responsibility**. Institution acknowledges and agrees that it is responsible for (A) the actions, performance, and conduct of the Principal Investigator and Sub-Investigator(s), and (B) the compliance by the Principal Investigator and Sub-Investigator with all of obligations as set forth in this Agreement and the Protocol. Any failure by the Principal Investigator or Sub-Investigator(s) to perform or satisfy an obligation under the Agreement or the Protocol that would, if done or caused by Institution, constitute a breach of this Agreement by Institution, shall be considered a breach of this Agreement by Institution.
	6. **Protocol Amendments**. Neither the Institution nor the Principal Investigator without prior approval of Sponsor may change the Protocol. Changes to the Protocol may only be made during the Study (“Protocol Amendments”) and by an authorized representative of Sponsor. Such Protocol Amendments are effective (a) when provided by Sponsor to the Principal Investigator; (b) when the Protocol Amendment has been approved by the IRB (if required); and (c) when the Protocol Amendment has been approved by any regulatory or governmental authority, including but not limited to the Food and Drug Administration (the “FDA”) and Centers for Medicare & Medicaid Services (“CMS”) (collectively, the “Regulatory Authority”). Notwithstanding the foregoing, and subject to any Applicable Laws, a deviation from the Protocol will be allowed without a Protocol Amendment only if generally accepted standards of clinical research and medical require such deviation from the Protocol. In such instance, 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. Any such deviations from the Protocol shall be accurately reported to Sponsor by the Principal Investigator on the appropriate form as soon as possible, after the deviation occurs and shall be managed in full compliance with the Protocol and all Applicable Laws. 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 21.
1. **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:
	1. Institution represents and certifies that: (a) it and the Institution Personnel have and will maintain throughout the Study all training, licenses, approvals, certifications, equipment not otherwise provided by Sponsor, and information necessary for safely and properly conducting the Study in accordance with the Protocol; (b) all Institution Personnel are currently in compliance with all Laws regarding human research studies, are not ineligible, debarred or disqualified from performing the duties assigned to them under this Agreement or the Protocol, and are not 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; and (c) it will not knowingly allow any person or entity that is ineligible, debarred, or disqualified to work on the Study or render any services required under this Agreement or the Protocol 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. Institution will promptly notify Sponsor if it becomes aware that any person who assists in performing the Study becomes so debarred during the term of the Study or within five (5) years thereafter; and
	2. Investigators represent and certify that (a) they are qualified by training and experience with appropriate expertise to conduct the Study and will, within ten (10) business days of their signature on this Agreement or Exhibit A, as applicable, provide Sponsor: (i) a current, accurate Curriculum Vitae (“CV”); (ii) to the extent not covered by the CV, a written statement of the Investigator’s training and experience in medical device clinical research relevant to the Study, including the dates, location, extent and type of that experience, in accordance with 21 C.F.R. § 812.43; and (iii) a signed Investigator Agreement in the form attached as Exhibit A to this Agreement.
	3. Institution certify on behalf of Investigators that they have never been declared by any Regulatory Authority to be ineligible to receive investigational devices (or otherwise been disqualified from receiving such devices) and have never participated in a clinical investigation or other research activity which was terminated by any Regulatory Authority, any IRB or sponsor for reasons other than completion of the research project or reasons not related to Institutions actions or missactions. The Investigators each individually certify that (i) they have never been subjected to any restrictions or sanctions related to allegations of academic, research or professional misconduct, and are not currently the subject of any proceeding which may lead to such sanctions; (ii) they are currently, and during the term of the Study will remain, in compliance with all applicable training, licenses, certifications and governmental requirements, including without limitation, being licensed to practice medicine in the state in which Institution is located; and (iii) they are not ineligible, debarred or disqualified from performing their obligations under this Agreement. Principal Investigator further certifies that he or she will not at any time employ in connection with this Agreement any person or entity that is ineligible, debarred, or disqualified from rendering such services. Principal Investigator agrees to promptly notify Sponsor in writing if he/she becomes aware of any noncompliance with the requirements of this Section.
	4. 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**”). Principal Investigator shall supervise all testing of the Study Device at all times during the course of the Study. Institution represents, to the best of its knowledge after reasonable inquiry, that neither it nor any Study Personnel are under any conflicting obligation or legal impediments that (a) will materially interfere with the performance of Institution’s obligations under this Agreement or (b) will impair acceptance of the resulting Study Data by any Regulatory Authority.
	5. Institution shall require that only individuals and entities which are aware of and bound by the obligations of this Agreement and the Protocol, including, without limitation, provisions regarding confidentiality Publication, and ownership of Study Data and Intellectual Property, will be allowed to work directly on the Study.

**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**Institution shall not enter into any other agreement that will prevent the performance of its obligations herein during the term of the Agreement..

1. **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 (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 Agreement 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.
2. **SUBJECT ENROLLMENT AND INFORMED CONSENT**.
	1. **Subject Enrollment**. The Principal Investigator shall enroll subjects into the Study in accordance with the Agreement and the 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 that the Study is part of a multi center Study (a “**Multi-Center Study**”), and therefor, when the enrollment goal for the 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.
	2. **Informed Consent**. Prior to enrolling any research subjects in the Study, Institution, Sponsor and the IRB shall agree upon and approve the information to be provided to potential Subjects of the Study to secure their informed consent, including without limitation any information about compensation being provided to Subjects for participation in the Study (the “**Informed Consent Materials**”), which complies with the requirements of all Applicable Laws, including 21 C.F.R. Part 56. Principal Investigator, on behalf of Institution, shall obtain the written informed consent of each Subject prior to any screening or participation in the Study using the Informed Consent Materials, and in accordance with Applicable Laws. The Investigators shall use only the Informed Consent Materials in the form approved by Sponsor, Institution and the IRB. None of the Informed Consent Materials shall be modified or amended in any manner without written approval of Sponsor and the IRB.

* 1. **Adverse Events**. For the Study, the Institution and Principal Investigator shall notify Sponsor of any information concerning any Study Device deficiency and any serious or unexpected event, injury, toxicity or sensitivity reaction, even if not a subject injury, and the severity thereof, associated with the Study Device in accordance with the Protocol for the Study with respect to the reporting of adverse Subject experiences and Applicable Laws. If the adverse event requires action by Sponsor to prevent an unreasonable risk of substantial harm to the public health, then notice of such event shall be given by telephone or e-mail (with a follow-up by mail, e-mail or facsimile as appropriate to Sponsor and the IRB (as required by applicable Law and IRB policy) as soon as possible, but in no event later than forty-eight (48) hours after such event. In addition, Principal Investigator will immediately notify Sponsor and the IRB in writing of any Unanticipated Adverse Device Effect (“**UADE**”), but in no event later than ten (10) working days after such UADE. Principal Investigator will obtain and maintain in his/her files all pertinent clinical data, including without limitation, clinical records, clinical information and clinical judgments from colleagues who assisted in the treatment and follow-up of the research subject, relating to all adverse events.

During the Study, Sponsor shall promptly, or  in a timely manner, appropriate to the level of risk involved, provide the Principal Investigator, or designee at the Institution, with the written report of any findings, including Study results and any routine monitoring findings in site monitoring reports, and data safety monitoring committee reports including, but not limited to, data and safety analyses, and any Study information that may affect the safety and welfare of current or former Study Subjects. Following the completion of the Study, if Sponsor becomes aware of any findings that would directly affect the safety of the Study Subjects, Sponsor shall promptly, or in a timely manner, appropriate to the level of risk, notify the Principal Investigator, or designee at the Institution, of such finding so that Institution may communicate such findings to the Study Subject. Sponsor’s post-Study reporting obligation shall continue until the completion of the final report for the Study. Institution and/or Principal Investigator will communicate findings to the IRB and Study Subjects, as appropriate.

1. **COMPENSATION; FAIR MARKET VALUE**.
	1. **Compensation**. For the services to be rendered under this Agreement, Sponsor shall pay the Institution in accordance with the Budget set forth in **Exhibit B**. The Parties acknowledge that the amounts to be paid by Sponsor under this Agreement for the 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 11, 15.7, 16 and 19.4, the Institution acknowledges and agrees that for the Study, the payments made by Sponsor under this Section represent Sponsor’s total obligations under this Agreement with respect to the Study, and fully cover the costs of conducting such Study. Unless otherwise provided in the Agreement, the 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) knowingly 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.
	2. **Fair market value**. For the 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 Agreement 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.
2. **COMPLIANCE WITH LAWS AND ACCEPTED PRACTICE.**
	1. **Compliance with Laws**.
		1. The Parties will perform their obligations hereunder and conduct the Study in compliance with all Applicable Laws, including without limitation, FDA regulations in 21 C.F.R. Parts 50 (Protection of Human Subjects), 54 (Financial Disclosure), 56 (IRBs), and 812 (IDEs). Additionally, the Investigators will abide by (a) all conditions of approval of the Study imposed by the reviewing IRB or any Regulatory Authority, (b) general standards of good clinical practice, (c) the Protocol and (d) any other written instructions provided by Sponsor.
		2. The Investigators acknowledge that compensation provided under this Agreement may affect the amount of reimbursement they obtain from third party payers for test/procedures performed in conjunction with the Study. The Investigators agree to comply with all Applicable Laws and the guidelines for such payers in seeking reimbursement for any Study-related test/procedures, including without limitation, reimbursement for any Study-related injuries to a research subject. For any Study procedure, test, treatment or other material or service provided or paid for by Sponsor, the Investigators will not knowingly seek or accept from research subjects, any third-party payers, or any other person whether private or government funded, compensation in addition to or in lieu of compensation provided by Sponsor, and will not assist research subjects in obtaining any such compensation. Sponsor further agrees to ensure that any compensation it provides to other Parties in conjunction with the Study does not exceed fair market value for services rendered and facilities provided.
		3. The Parties and their respective affiliates, as applicable, will comply with (a) the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)) and, to the extent possible, the related safe harbor regulations; (b) the Limitation on Certain Physician Referrals, also referred to as the “Stark Law” (42 U.S.C. § 1395nn); (c) the Federal False Claims Act (31 U.S.C. § 3729 et. seq.); (d) the Medicare and Medicaid program requirements as applicable; (e) the Foreign Corrupt Practices Act 1977 of the United States of America (“FCPA”); and (f) any other applicable anti-corruption legislation. In particular, the Parties agree that the compensation payable hereunder is fair market value for services rendered and no part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business. If any portion of this Agreement 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 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.
		4. Each Party agrees to timely notify the other Party in the event that it has identified potential violations of applicable Laws associated with its performance of the Study and describe the nature of such potential violation. In the event that any part of this Agreement or the Protocol is determined to violate any Laws, the Parties agree to negotiate in good faith revisions to the provision(s) which are in violation. In the event the Parties are unable to agree to new or modified terms as required to bring the entire Agreement into compliance, any Party may terminate this Agreement immediately upon written notice to the other Parties.
	2. **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.
	3. **Financial disclosure by Sponsor**. Institution and Principal Investigator understand that Sponsor is required pursuant to Applicable Laws requiring financial transparency, including but not limited to the Physician Payment Sunshine Act and its implementing regulations (the “**Sunshine Act**”), as well as best industry practices 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 the 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 will have the right (but not the obligation, unless such disclosure is mandated by Law) to: (a) display publicly, including on its web site, information regarding all payments or transfers of value made by Sponsor to the Investigators in connection with the Study; and (b) disclose this information to affiliated hospitals and any Regulatory Authority.
3. **STUDY DEVICE**. 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.

**9.1** **Use of the Study Device**. The Parties acknowledge the Study Device shall only be used as described in the Protocol and in compliance with Applicable Laws, including those pertaining to investigational device exemptions.

**9.2** **Study Materials**. The materials required by Institution and Investigator to conduct the Study per the Protocol are “Study Materials”. Institution will receive from Sponsor, without charge, the Study Device for each Study Subject during the enrollment period. Institution shall purchase all other Study Materials for the Study as required under the Protocol, including any other devices to be used under the Protocol as a control therapy. Institution’s receipt, storage and handling of the Study Device will be in compliance with all regulations, the Protocol and Sponsor instructions. Institution and Principal Investigator shall use the Study Device and all other Study Materials supplied by Sponsor hereunder (or on its behalf) solely as specified in the Protocol and for no other purpose.

**9.3** **Study Device Coverage**.In no event shall Institution and Principal Investigator seek or collect reimbursement from any governmental agency (including Medicare or a state agency such as Medicaid which reimburses for health care services) or any other payer, including Subjects, for any Study Device, equipment, tests, items, supplies or other materials that are provided to Research Institution or Principal Investigator by Sponsor at no charge, replaced at no charge, or which are reimbursed by Sponsor under this Agreement.

**9.4** **Return of Study Device**. All items, supplies or other materials provided by Sponsor to the Research Institution without charge shall be returned by the Research Institution and Principal Investigator at the completion or termination of the Study, as applicable. Should any Study Device be damaged or explanted for any reason, Research Institution and Investigators shall, at Sponsor’s expense, promptly return such Study Device to Sponsor or, at Sponsor’s direction, send it to a third-party for analysis.

**9.5** **Investigational Nature**. 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, relating to the Study Device. The Parties further agree that Sponsor’s efforts in this regard are not intended to induce the Research Institution, the Principal Investigator or any other individual to use or arrange the use of the Study Device except for the sole and limited purpose of conducting the Study.

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 THE APPLICABLE PROTOCOL WILL NOT INFRINGE THE RIGHTS, PATENT OR OTHERWISE, OF ANY THIRD PARTY.
2. **RECORDS; REPORTS; AND REGULATORY ASSISTANCE**.
	1. **Study Documentation**. For the 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 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.
	2. **Entry of Data**. 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. The Study will use 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 11.3). The case report form 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 case report form 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 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.
	3. **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 (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. Institution shall ensure that any CRFs are completed in an accurate, complete, and timely manner. The Institution shall provide the final CRFs required by the Study as set forth in the Agreement or such later date as Sponsor may reasonably require.
	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, premarket approval applications (PMA) for the Study Device, 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.

**11.5 Security of Records**. At a minimum, the Investigators shall (a) maintain and store the Study Documentation and Study Data in a secure manner with physical and electronic access restrictions, and environmental controls appropriate to the applicable data type and in accordance with applicable industry standards; and (b) protect the Study Documentation and Study Data from unauthorized use, access, duplication, disclosure, loss or damage.

**11.6** **Record Retention**. Institution shall retain Study records for the retention period required by any Applicable Laws following the completion, suspension 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.

1. **PRIVACY AND HIPAA**.
	1. **Protected Health Information**. The Institution and the 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 conduct the Study in accordance with all Applicable Laws, including HIPPA, and handle all Study Documentation (including Subjects’ medical records) in accordance with all applicable HIPAA requirements and all other Applicable Laws. Institution and Principal Investigator shall ensure that an authorization from each Subject is obtained prior to performance of any Study procedures, allowing the Investigators to disclose all required Study results described in the Protocol, including without limitation Protected Health Information (as defined in HIPAA) in medical records, billing information, and cost analyses, to Sponsor, its representatives, and Regulatory Authorities (the “Authorization”). The Authorization shall be submitted to Sponsor for review and approval prior to its use in connection with the Study. The Investigators shall use only the Authorization in the form approved in writing by Sponsor. If the Authorization form is modified, Principal Investigator will re-submit the modified Authorization form to Sponsor for review and approval, not to be unreasonably withheld, prior to use in the Study. Sponsor shall collect, use, store, access, and disclose Protected Health Information (as defined in HIPAA) collected from Subjects only as permitted by the Subject Consent or Authorization form obtained from a Subject. Principal Investigator shall promptly inform Sponsor of any failure to obtain an Authorization as required by this Section.

**12.2 Sponsor Not Covered By HIPAA**. Sponsor represents and covenants, and the Institution and the Principal Investigator acknowledge such representation 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.

1. **AUDIT, MONITOR AND REVIEW**. For the 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 (as defined in Section 11.1), Source Documents (as defined in Section 16.7), any other nonfinancial books, records, Study Data (as defined in Section 17.1) and Work Product (as defined in Section 16.4) relating to the Study, and all required licenses, certificates and accreditation; (d) study, inspect and test all Study Devices after explant if such Study 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. Any Confidential Information of the Institution 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 15. 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 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.
2. **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 immediately notify Sponsor 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. Sponsor shall have no obligation to compensate Institution for any expenses relating to a for cause audit initiated by FDA or other Regulatory Authority based on any alleged or actual misconduct of the Institution.
3. **CONFIDENTIAL INFORMATION.**
	1. **Definition**. 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, 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, Study Data, trade secrets, 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.
	2. **Exceptions to Confidentiality**. Confidential Information does not include any information that: (a) was lawfully obtained from a third-party without breach of any obligation of confidentiality; (b) is or becomes publicly-available through no act or violation of any obligation of this Agreement; (c) is independently developed by a Party to this Agreement as evidenced by written records kept in the ordinary course of business; or (d) is published in accordance with Section 17 herein. 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 Study 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.
	3. **Institution’s Obligations**. In conducting the Study under this Agreement, Sponsor will be required to disclose Confidential Information to Institution and Principal Investigator, and Institution and Principal Investigator will be required to use Confidential Information, which is the exclusive property of Sponsor. All Confidential Information disclosed by Sponsor shall be marked or identified as Confidential Information, 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 Confidential Information. To protect the Confidential Information, Principal Investigator and Study Personnel agree as follows: (a) to use such Confidential Information for the sole purpose of performing their obligations under this Agreement during the term of this Agreement; (b) to not disclose Confidential Information to any third party for a period of five (5) years after the expiration or termination of the Study without Sponsor’s written consent; (c) to limit dissemination of Confidential Information to only those Study Personnel, employees, agents, or consultants having a “need to know”; (d) to advise the Study Personnel, and each employee, agent, or consultant who receives Confidential Information of the confidential nature of such information; (d) to implement appropriate agreements, policies and/or procedures in place with such employees, agents, and consultants sufficient to enable the Study Personnel, employee, agent or consultant to comply with the confidentiality obligations contained herein; and (e) to immediately notify Sponsor upon the Institution or the Principal Investigator’s discovery of any loss or compromise of the Confidential Information.
	4. **Sponsor’s Obligations**. In conducting the Study under this Agreement, Institution and Principal Investigator may provide Confidential Information to Sponsor, 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. All Confidential Information disclosed by Institution or Principal Investigator shall be marked as Confidential Information, 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. To protect the Confidential Information, Sponsor agrees as follows: (a) to use such Confidential Information for the sole purpose of performing its obligations under this Agreement during the term of this Agreement; (b) to not disclose Confidential Information to any third party for a period of five (5) years after the expiration or termination of the Study without Institution’s written consent; (c) to limit dissemination of Confidential Information to only those employees, agents, or consultants having a “need to know”; (d) to advise the Study Personnel, and each employee, agent, or consultant who receives Confidential Information of the confidential nature of such information; (d) to implement appropriate agreements, policies and/or procedures in place with such employees, agents, and consultants sufficient to enable the Study Personnel, employee, agent or consultant to comply with the confidentiality obligations contained herein; and (e) to immediately notify Institution of Sponsor’s discovery of any loss or compromise of the Confidential Information.
	5. **Trade Secrets**. 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 is subject to the Institution and the Principal Investigator’s publication rights as set forth in Section 15.
	6. **Return of Confidential Information.** Promptly upon the expiration or termination of this Agreement, or upon the request of Sponsor, the Institution and Principal Investigator will either, at Sponsor’s direction, destroy or return to Sponsor all Confidential Information belonging to Sponsor, together with all copies, recordings, abstracts, notes, reproductions of any kind made from or about the documents and tangible items or the information contained therein; 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.
	7. **Compelled Disclosures**. 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 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.
	8. **Irreparable Harm**. Institution and Principal Investigator acknowledge that a breach of this Section may cause irreparable damage that cannot be addressed adequately by money damages. In addition to any other remedies that may be available, Sponsor is therefore entitled to seek injunctive relief to prevent or restrain a breach of this Section, without having to post bond or other security.
4. **OWNERSHIP OF MATERIALS, INTELLECTUAL PROPERTY AND WORK PRODUCT.**
	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. 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 Principal Investigator and other personnel for whom such access and use is required to conduct the applicable 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 the Agreement, or (iii) as otherwise reasonably requested in writing by Sponsor.

* 1. **Inventions**. Any invention, technologies, innovation, discovery, ideas, processes, techniques, algorithms, software, methods, discoveries, improvements, devices, products, concepts, designs, prototypes, samples, models, technical information, materials, drawings, trade secrets and specifications and other proprietary ideas (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. Sponsor shall have all right, title and interest to Sponsor Intellectual Property. 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 constitute “Other Inventions” shall be determined in accordance with U.S. Patent Law. For each Other Invention developed solely by Institution and/or Investigator, Sponsor shall have the option to negotiate for a non-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 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.
	2. **Retained Rights**. Each Party to this Agreement shall retain all Rights in any Intellectual Property, patent, patent application, trade secret, know-how, trademarks, copyrights, and other information 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.
	3. **Work Product**. For the 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 Agreement 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 17.2. 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.
	4. **Assistance**. The Institution shall, and shall cause the 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 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.
	5. **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 Agreement.
	6. **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 “**Source Documents**”), and may use such records Source Documents, as it deems reasonable and appropriate in accordance with Applicable Laws.

1. **PUBLICATION AND USE OF STUDY RESULTS**.
	1. **Study Data**. For the Study, the Institution and the Principal Investigator acknowledge and agree that the data collected during the Study (“Study Data”), except as otherwise provided in this Agreement 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. The Study is a Multi-Center Study, therefore, 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”). 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 Principal Investigator at the completion or earlier termination of the Study.
	2. **Publication and Use of Study Data**. Unless otherwise specified in the Agreement, 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 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 Agreement) 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.
	3. **Sponsor Review**. Unless otherwise specified in the Agreement, 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 Agreement shall not be deemed Confidential Information. 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. To the extent that any provision of this Section may be inconsistent in any respect with any statements about publication policy set forth in a Protocol, the provisions of this Section shall control.
	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.
	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, non-exclusive and 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 the Study and each Multi-Center Study.
	6. **Clinical Study 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.
2. **USE OF NAME; ADVERTISING**.
	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 Study registries, (iii) communications with regulatory authorities, (iv) publications and presentations, (v) public disclosures required by law, regulation, or regulatory authorities, and (vi) any clinical Study website and similar public notifications of clinical studies 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 Study registries for: (i) C.V.s, (ii) internal reports, (iii) publications and presentations made pursuant to Section 17, (iv) grant applications to government and other funding sources, (v) required government reports and filings, (vi) Institution's clinical studies website and similar public notifications of clinical studies offered by Institution; and (vii) conflict of interest disclosures.
	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.
3. **INDEMNIFICATION, INSURANCE AND LIMITATION OF LIABILITY**.
	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, or proceedings that may be brought or instituted (each a “**Claim**”), and all 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 caused by (a) a defect or malfunction of the Study Device used in accordance with the Protocol; (b) Sponsor’s negligence or misconduct; (c) breach of this Agreement; or (d) Sponsor’s failure to comply with Applicable Laws. Sponsor shall have no obligation to defend or indemnify if the Claim or Losses were caused by: (i) a material failure by an Institutional Indemnified Party to comply with the Protocol, Sponsor's instructions and instructions for use for the Study Device, or the terms of this Agreement, allowing for deviations for Subject safety, and/or with state or federal statutes or regulations, including FDA regulations; (ii) the negligence or misconduct of such Institutional Indemnified Party, provided that complying with the Protocol, Sponsor's instructions and instructions for use for the Study Device, or the terms of this Agreement shall not be considered negligence for purposes of this exception; (iii) a failure to comply with any Applicable Law or regulation by one or more of the Institutional Indemnified Parties; or (iv) use of a control device in the Study.
	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 any Claims and Losses to the extent directly attributable to (a) prior treatment by Institution, the Principal Investigator, or any Sub-Investigator(s) giving rise to the condition for which the Study Device is used in connection with the Study; (b) the negligence, recklessness, or willful misconduct of one or more of the Institutional Indemnified Parties; (c) any failure of one or more of the Institutional Indemnified Parties to adhere to terms of the Protocol, Sponsor's instructions and instructions for use for the Study Device, or the terms of this Agreement; or (d) a failure to comply with any Applicable Law or regulation by one or more of the Institutional Indemnified Parties.

* 1. **Indemnification Procedures**.
		1. **Conditions of Indemnity**. The Party seeking indemnification pursuant to this Section (each an “**Indemnitee**”) will promptly notify the other Party (each an “**Indemnitor**”) of any 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.
		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.
	2. **Reimbursement of Medical Expenses for Subject Injury**
		1. Definition*.* “**Subject Injury**” means bodily injury or death to a Study Subject caused by use of the Study Device or performance of any investigational non-standard of care medical procedure required by the Protocol that is different from the medical procedure the Study Subject would have received if the Study Subject had not been enrolled in the Study, in each case, in accordance with the Protocol, and written instructions of Sponsor or its representatives, and this Agreement. The term Subject Injury does not include the underlying or pre-existing condition for which the Study Device is being investigated, including the natural progression of such underlying or pre-existing condition, or injuries arising from using currently approved therapies for the Study subject’s condition, including without limitation, the use of any FDA-approved devices. Sponsor shall not be responsible for the cost of treating a Subject Injury that such Subject Injury was caused by: (a) the negligent, grossly negligent, or wrongful acts or omissions of the Institution or Investigator (b) Institution or Investigator’s failure to follow Applicable Laws or to conform to reasonable and prudent clinical practices, (c) failure of the Institution or Investigator to comply with the Protocol, or the written instructions provided by Sponsor or its representatives, or any misuse of the Study Device, or (d) any Study Subject’s failure to follow the instructions provided in the informed consent.
		2. Coordination: In the event of a Subject Injury, Institution shall coordinate and manage any requests for payment or reimbursement from a Study Subject for treatment of a Subject Injury, and shall provide to Sponsor or its designee in a timely, accurate, and complete manner, such supporting documentation and reports, including, the social security number of the Study Subject and such other information relating to the treatment and insurance coverage of the Study subject as may be reasonably requested by Sponsor to assess whether any such injury is a Subject Injury and/ or as appropriate to comply with applicable laws and regulations, including the Medicare Mandatory Reporting Provisions of the Medicare, Medicaid and SCHIP Extension Act of 2007 (42 U.S.C. 1395y(b)(7) and (b)(8)), as amended or supplemented from time to time.
		3. Reimbursement: Medicare and private payers cover the routine costs of qualifying clinical trials, and reasonable and necessary items and services used to diagnose and treat complications arising from the participation of the clinical trial. Sponsor has obtained CMS Approval for the Study, and Institution shall ensure insurance pre-authorization is obtained for all Study Subjects before enrollment in the Study. Any medical expenses incurred by Institution for the diagnosis or treatment of an injury or illness to a Study Subject due to participation in the Study, including a Subject Injury, shall be billed to the Study Subject’s insurer, government program or other payer. Sponsor shall have no obligation to reimburse Institution, any other medical provider, or the Study Subject for the medical costs or expenses relating to the diagnosis or treatment of any injury or illness to a Study Subject, including for a Subject Injury. Sponsor, in its sole discretion, may pay for any portion of the expenses of care or treatment provided to such Study Subject, even if it has not been demonstrated that an injury or illness is a Subject Injury. Sponsor’s agreement to pay under this Section 19.4 does not constitute an admission of liability for any Subject Injury, which ultimately could be determined only through an adjudication process, or as a settlement or compromise of any potential future liability claim.

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* 1. **Insurance**.

**Sponsor Insurance**. Sponsor will take out or maintain at the minimum the following insurance coverages: (i) product 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. Sponsor shall produce to Institution, upon request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect during the term of this Agreement, and if the policy is claims-made, such policy shall be maintained with an appropriate extended reporting period as determined by Sponsor.

* + 1. **Institution Insurance**. Institution will take out or maintain at the minimum the following insurance coverages with insurers of an AM Best Rating of A VIII or better: general liability insurance to cover the potential liability of Institution, the Research Staff, the Principal Investigator and any other employees and Agents involved with the conduct of the Study pursuant to this Agreement, with shall include limits of at least $5,000,000 per occurrence and $5,000,000 in the aggregate. This policy will state it is Primary and Non-Contributory with regards to Sponsor’s insurance. This policy will contain a waiver of subrogation in favor of Sponsor.  Medical Malpractice Insurance to cover the potential liability of medical professionals which shall include limits of at least $5,000,000 per claim and $5,000,000 in the aggregate. This policy will state it is Primary and Non-Contributory with regards to Sponsor’s insurance. This policy will contain a waiver of subrogation in favor of Sponsor. The limit requirements for General Liability and Medical Malpractice may be met with any combination of Primary and Excess Liability insurance policies.  Workers Compensation insurance as required by the local jurisdiction, including a Waiver of Subrogation in favor of Sponsor. Institution shall produce to Sponsor, upon request, copies of insurance certificates, together with evidence that the policies to which they refer remain in full force and effect during the term of this Agreement and, if the policy is claims-made, for five (5) years thereafter.  Sponsor shall be named as an Additional Insured on Institution’s General Liability policy. The terms of any insurance or the amount of coverage shall not relieve Institution or the Principal Investigator of any liabilities under this Agreement. Where the Institution cannot cover Agents under its insurance, it shall verify that such Agents have sufficient insurance and inform the Sponsor of such insurance upon request.  Institution agrees to notify Sponsor within twenty (20) days of any notice of cancellation or non-renewal of, or material change in, or claim against, its insurance coverage.
		2. **Policy**. The coverage shall remain in place throughout the term of the 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
		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.
	1. **LIMITATION OF LIABILITY**. EXCEPT FOR EACH PARTY’S, INDEMNITY AND DEFENSE OBLIGATIONS UNDER SECTION 19 FOR CLAIMS ASSERTED BY THIRD PARTIES OR DAMAGES ARISING FROM EITHER PARTY’S NEGLIGENCE, 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, THE PROTOCOL OR 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.
1. **TERM**. This Agreement shall be effective as of the Effective Date and shall continue until the earlier of (i) the completion of the Study, or (ii) the date that this Agreement is terminated in accordance with Section 21.
2. **TERMINATION**.
	1. **Termination by Sponsor**. Sponsor may suspend or terminate the Study or terminate this Agreement, in whole or in part, with or without cause at any time, effective upon thirty (30) days advance written notice or such other period of time as set forth in the written notice.
		1. In the event of a material breach of this Agreement by the Institution or Principal Investigator, Sponsor may (A) immediately suspend the Study, and/or (B) terminate this Agreement, provided that for subsection (B) the breaching Party is given written notice of the nature of the default, an opportunity to cure such default within a period of ten (10) days after the breaching Party’s receipt of such notice, and such default is not cured during such period.
		2. Sponsor may terminate this Agreement, on written notice to Institution, immediately upon suspension or termination of the Study
		3. Sponsor may terminate this Agreement in accord with Section 3.1.
	2. **Termination by Institution**. Institution may terminate this Agreement in the event of a material breach of this Agreement by the Sponsor, provided that Sponsor is given written notice of the nature of the default and the breaching Party is afforded an opportunity to cure such default within a period of thirty (30) days after Sponsor’s receipt of notice and such default is not cured during such period*.*
	3. **Suspension of Study**. Performance of this Agreement may be suspended by any Party at any time for health or safety reasons, if, in the reasonable opinion of Principal Investigator, Institution, or Sponsor, continuation represents an unacceptable risk to the Subjects. In the event of any such determination by Institution and/or Principal Investigator, Institution and/or Principal Investigator shall promptly notify Sponsor of the same prior to suspending performance, and, promptly after such notification, shall provide Sponsor with a detailed written explanation for the suspension of the Study, including any associated documentation in support thereof. In the event of such suspension of the Study, Institution and Principal Investigator shall immediately cease enrollment of Study Subjects into the Study.
	4. **Effect of Termination**.
		1. Immediately upon receipt of a notice of termination, the Principal Investigator and Principal Institution shall stop screening and enrolling subjects into the Study and shall, as directed by Sponsor, cease conducting Study Activities on Subjects already enrolled in the Study, as soon as reasonably possible, and to the extent medically permissible, to minimize any adverse medical effect to such enrolled Study Subjects and to cease incurring any additional Study expenses. Principal Institution and Investigator shall continue to perform the follow-up testing and provide the data required under the Protocol on subjects already participating in the Study, unless instructed otherwise by Sponsor in writing, and the terms of this Agreement shall continue to apply to such follow-up testing and data. Sponsor or its designee shall have the right to assume full control of the terminated Study. Principal Investigator and Institution shall provide such other reasonable assistance, at Sponsor’s expense, as is necessary to ensure a smooth and orderly transition of the Study that will not involve any disruption of the Protocol, if the Study is continuing, and to ensure the full transfer of Study Documentation and Sponsor’s ability to verify all data.
		2. Within thirty (30) days of termination of this Agreement or completion of the Study (whichever comes first), Principal Investigator will submit a final written report to Sponsor regarding the Study, and Institution will return any Study Devices, Sponsor Materials, and any other materials and equipment that were furnished to the Institution by Sponsor.
		3. Within ninety (90) days after the termination of this Agreement, an accounting shall be conducted by Institution, subject to verification by Sponsor, and Institution shall deliver to Sponsor such final accounting of all Study Subjects participating in the Study and the visits completed in accordance with the Study during the term of this Agreement. Within thirty (30) days of delivery or receipt of the final accounting, Institution shall refund to Sponsor any excess amounts paid by Sponsor. Only those services and expenditures compensated under this Agreement shall be compensated upon termination, and Sponsor shall not be responsible for any lost profits or lost opportunities.
		4. Termination of this Agreement by any Party will not affect the rights and obligations of the Parties accrued prior to the Effective Date of the termination. Sponsor agrees to reimburse the Payee for any prepaid or committed expenses that it has agreed to support and which the payee is reasonably unable to recover; provided, however, that Sponsor shall have no obligation to pay for work not performed in compliance with this Agreement and the Protocol. If this Agreement is terminated prior to completion of the Study, Principal Investigator will submit an investigator’s report to Sponsor (which will be in a form acceptable to Sponsor), for the completed portion of the Study.
		5. The Parties’ respective rights and obligations set forth in Section 7 (other than the first sentence), Section 8.2 and 8.3 (Financial Disclosures), Section 9 (Study Device), Section 10 (Disclaimer), Section 11 (Records; Reports), Section 12 (Privacy & HIPPA), Section 13 (Audit), Section 14 (Regulatory Inspections), Section 15 (Confidentiality), Section 16 (Ownership and Intellectual Property), Section 17 (Publication), Section 18 (Use of Name; Advertising), Section 19 (Indemnification and Insurance), Section 21 (Termination), Section 26 (Notices), Section 29 (Waiver), Section 30 (Inconsistency), Section 31 (Construction), Section 33 (Force Majeure) Section 34 (No Third Party Rights) shall indefinitely survive the expiration or termination of this Agreement to the extent necessary to preserve such rights and obligations.
3. **INDEPENDENT CONTRACTOR**. The relationship created by this Agreement is that of a contractor of services and nothing contained herein is intended to, nor will it create, the relationship of partnership, joint venture, agency or employment. The Investigators will not have the right or power to bind Sponsor to any contracts or agreements with any third party, nor will the Investigators have the right or power to direct any operations of Sponsor. Personnel employed or engaged by Institution will be deemed employees of Institution for purposes of this Agreement and will not, for any purpose, be considered employees or agents of Sponsor. Institution assumes full responsibility for the actions of Study Personnel while performing services pursuant to this Agreement and will be solely responsible for their supervision, daily direction and control, and payment of salary (including without limitation withholding of income taxes and social security), workers’ compensation and disability benefit.

1. **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 such assigning party. In the case of assignment of this Agreement, the assigning party shall provide prompt written notice to the other party. Any authorized successor shall expressly assume in writing the obligation to perform in accordance with the terms and conditions of this Agreement. Any other purported assignment shall be void.
2. **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.
3. **GOVERNING LAW**. The Parties agree to remain silent regarding the governing law, venue and jurisdiction.
4. **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 Principal Investigator, to:

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| --- | --- | --- | --- |
| Address: | Conformal Medical, Inc. | Address: | [Insert Institution address] |
| 15 Trafalgar SquareSte. 101 |  |
| Nashua, NH 03063 |  |
|  |  |  |  |
| Attention: | Melissa Farina Chief Financial Officer | 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. 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 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.

1. **ENTIRE AGREEMENT**. This Agreement, including the exhibits, appendices, schedules or other attachments referenced in this Agreement, constitutes the entire Agreement among the Parties and supersedes any and all prior agreements, understandings or arrangements, whether oral or written. Each Party confirms that it has independently entered this Agreement based on its own judgment and in consultation with its own legal counsel, and is not relying on any representations, warranties or covenants of any other party except as specifically set out herein. The Parties executing this Agreement have the full right and authority to enter into this Agreement on behalf of themselves and/or any person or entity on behalf of whom this Agreement is entered, whether in a representative or agency capacity. All exhibits, appendices, schedules or other attachments referenced in this Agreement are hereby incorporated into this Agreement by such reference and are deemed to be an integral part of this Agreement. The Parties may amend or modify this Agreement in such manner as may be agreed only upon a written instrument executed by authorized representative of all Parties. For the avoidance of doubt, the signatures of any Sub-Investigators are not required on any amendment to this Agreement. Electronic mail will not suffice to constitute written consent to amend this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud.
2. **AMENDMENT**. Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each Party.
3. **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.
4. **INCONSISTENCY**. The terms of this Agreement and the Protocol shall take precedence over other documentation, including but not limited to the Subject Consent in the interpretation and resolution of disputes concerning this Study. In the event of any inconsistency between this Agreement 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 Agreement shall prevail.
5. **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.
6. **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. Signature pages of this Agreement may be exchanged by facsimile or electronically as a portable document format (pdf) file or similar electronic file and such signature pages will be deemed originals and will have the same effect as physical delivery of the paper document bearing the original signature.
7. **FORCE MAJEURE**. No Party shall be in default hereunder by reason of any failure or delay of performance if and to the extent such failure or delay is caused by circumstances beyond its reasonable control and that by the exercise of due diligence it is unable to prevent, provided that the non-performing party uses its reasonable efforts to overcome the same. Such causes shall include, without limitation, accidents, storms, floods, other acts of nature or God, fires, explosions, riots, acts of aggression, war or civil disturbance or disorders, strikes or other labor disputes of any kind, delays in transportation, inability to obtain necessary labor, supplies, or manufacturing facilities, embargoes, and other governmental actions or regulations that would prohibit a Party from performing any other aspect of the obligations hereunder, failure of any governmental approval required for full performance, energy or other conservation measures imposed by law or regulation, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrence.
8. **NO** **RIGHTS OF THIRD PARTIES**. Nothing in this Agreement is intended to confer or shall be construed to confer any third-party beneficiary rights or the right to enforce any term of this Agreement on any non-party, including but not limited to Principal Investigator, Sub-Investigators, or any participant in the Study.

**THIS AGREEMENT IS EXECUTED** by the authorized representatives of Sponsor and the Institution as of the last date of the Parties’ signatures of this Agreement (“**Effective Date**”).

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| --- | --- |
| Conformal Medical, Inc. | [NAME OF INSTITUTION] |
| Signature:  | Signature:  |
| Name: Melissa Farina  | Name:  |
| Title: Chief Financial OfficerDate: ………………………………….

|  |  |
| --- | --- |
| READ AND ACKNOWLEDGE:PRINCIPAL INVESTIGATOR [PRINCIPAL INVESTIGATOR] | [NAME OF INSTITUTION] |
| Signature:  | Signature :  |
| Name:  | Name :  |
| Title: Date: …………………………………. | Title : Date: …………………………………. |

 | Title: Date: …………………………………. |

EXHIBIT A

INVESTIGATOR AGREEMENT (US)

**Protocol Title: CONFORM Pivotal Study (“Study”)**

I agree and/or certify that:

1. I will conduct the Study in accordance with this agreement, the Clinical Trial Agreement for the Study, all requirements of the Study Protocol, all applicable laws, rules, regulations and guidelines adopted into law relating to the conduct of clinical investigations, and good clinical practice (“GCP”) principles, all regulations of the FDA, and any conditions of approval imposed by my reviewing Institutional Review Board (IRB) or FDA.
2. I have read and acknowledged my responsibilities under the Clinical Trial Agreement for the Study and agree to be bound by the terms of the Clinical Trial Agreement, including but not limited to the confidentiality terms set forth therein.
3. I agree to abide by all of the responsibilities of Investigators addressed under [21 CFR Part 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812&showFR=1), Subpart E and Subpart G for the Study, including but not limited to the following:
* I will obtain written approval from the authorized IRB for the institution at which this Study will be conducted and submit certification of IRB approval and any conditions of this approval to Conformal Medical, Inc.
* I will ensure that Informed Consent and HIPAA Authorization are obtained from each subject participating in this Study in accordance with the informed consent regulation found in [21 CFR Part 50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1), and that a signed copy of the Informed Consent and HIPAA Authorization Form for each subject is available to Conformal Medical and its designated monitor and/or representatives.
* I will supervise all elements of the Study involving human subjects and will allow only those physician co-investigators listed on the Delegation of Responsibility Log to participate and/or perform activities for the purposes of the Study.
* I will ensure the accurate completion of protocol case report forms and I will submit completed protocol electronic case report forms, progress reports, and a final report to the sponsor at the time frames specified in the Protocol.
* I will direct the retention of required records and documents related to the Study during the investigation and for a minimum of two (2) years after the later of termination or completion of the Study or the date the records are no longer required to be maintained by Applicable Law.
* I agree to cooperate in the event of any Study-related audit by Conformal Medical or other regulatory agencies, as applicable. I agree to reasonably assist Conformal Medical or Conformal Medical’s representatives in conducting audits and resolving any discrepancies or errors with respect to the Study and all Study-related documentation.

4. I have attached my most recent curriculum vitae (CV) to this Agreement, signed and dated by me. My relevant qualifications, including dates, location, extent, and type of experience, are described in my CV, or in a separate statement that is attached, along with my CV, to this Agreement.

5. Regarding my previous participation in investigational or research activities **(check applicable statement)**:

 \_\_\_\_ I have never participated in an investigation or other research activity which was terminated by FDA, the IRB (or equivalent), or sponsor of a study

 \_\_\_\_ I have participated in an investigation or other research activity which was terminated by FDA, the IRB (or equivalent), or sponsor of a study. The specific circumstances leading to this termination and my role in the respective problems or issues and the resolution of these problems or issues are summarized in an attachment to this Agreement.

I further certify that I have not been debarred under the Food, Drug and Cosmetic Act. In the event that I become debarred or receive notice of an action or threat of an action with respect to my debarment during the term of this Agreement, I agree to immediately notify Conformal Medical and the authorized IRB for my study site.

6. I will certify and disclose sufficient and accurate financial information to allow Conformal Medical to submit a complete and accurate disclosure statement as required under 21 CFR Part 54. I will also notify Conformal Medical if my certified and disclosed financial information changes at any time during the Study and for one (1) year following completion of the Study.

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| **PRINCIPAL INVESTIGATOR AGREEMENT** |

|  |  |
| --- | --- |
| Name |  |
| Institution |  |
| Address |  |
| E-Mail |   |
| Telephone |  |

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| --- | --- | --- |
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Principal Investigator Signature Date

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| **ATTACHMENT A****SUB-INVESTIGATOR AGREEMENT** |

**Protocol Title: CONFORM Pivotal Study**

As a physician sub-investigator for above mentioned Study, I have read the foregoing and agree to be bound by its terms.

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Name of Sub-Investigator (Print)

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Signature Date

*Please print additional copies of this page, as needed, for additional sub-investigators.*

*[Remainder of Page Intentionally Left Blank]*

**EXHIBIT B**

**BUDGET**