CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("Agreement") is dated and effective as of the date of last signature below (the "Effective Date") by and between San Bernardino County on behalf of Arrowhead Regional Medical Center, a political subdivision of the State of California, ("Institution") which operates a licensed general acute care hospital with an address at 400 N. Pepper Avenue, Colton, CA 92324, **Aveera Medical, Inc.**, a corporation having its principal place of business at 929 Calle Negocio, Suite A, San Clemente, CA 92673 ("Sponsor"), and Samuel Schwartz ("Principal Investigator"). Sponsor, Principal Investigator, and Institution are herein referred to collectively as "Parties." Individually, each of Sponsor, Principal Investigator, and Institution is a "Party."

WHEREAS, Sponsor is a for-profit organization that intends to conduct a sponsored multicenter clinical trial, described in 1.1 below, involving the use of certain device(s) provided by Sponsor;

WHEREAS, Sponsor has determined that the Principal Investigator is qualified to conduct the clinical trial described in 1.1 below;

WHEREAS, Institution has appropriate facilities and personnel with the qualification, training, knowledge, and experience necessary to conduct such a clinical trial;

WHEREAS, the Study (as defined below) contemplated by this Agreement is of mutual interest and benefit to Institution, Principal Investigator, and Sponsor, and will further the instructional/educational and research/healthcare objectives of Institution; and

NOW, THEREFORE, in consideration for the mutual promises made in this Agreement and for good and valid consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the Parties agree as follows:

1. Scope of Agreement

1.1. Institution, in conjunction with the Principal Investigator, will undertake a sponsored multicenter clinical trial (the "Study") described in the protocol entitled, "Assessing the Safety and Efficacy of the CLTI treatment using the Boomerang™ Catheter", as may be amended from time to time and as approved by the Institutional Review Board ("IRB"), which is incorporated herein by this reference ("Protocol"). Institution shall ensure that the Study is initiated as soon as reasonably practicable after the date hereof. Institution shall use reasonable efforts to enroll Research Subjects (as defined below) at a rate of one Research Subject per month (such monthly rate, the "Enrollment Rate"), until the sample size objectives of the Study, as previously determined by Sponsor, have been achieved. Institution will use its reasonable efforts to only recruit Research Subjects in accordance with the Protocol. The Study will be conducted at the Institution under a medical staff member of the Institution, who will serve as the principal investigator for the Study, as contemplated in 21 C.F.R. § 312.60 who shall be Samuel Schwartz ("Principal Investigator"). As used herein, patients who meet eligibility criteria and enroll in the Study are referred to as "Research Subjects".

1.2. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or otherwise is unable to complete the Principal Investigator's responsibilities under this Agreement, Institution shall immediately notify Sponsor, and Institution and Sponsor shall endeavor in good faith to agree in writing upon an appropriate successor. If a mutually agreeable successor cannot be identified, Sponsor may terminate this Agreement upon written notice to Institution. In the event of such termination, Sponsor shall make payments to Institution for all services already actually provided under this Agreement up through the date of termination. Any successor Principal Investigator must sign a counterpart signature page hereto acknowledging receipt of the terms and provisions of this Agreement, whereupon such successor will thereafter be deemed to be the Principal Investigator under this Agreement for all purposes. Any Principal Investigator who is replaced pursuant to this Section 1.2 will be required to continue to comply with the obligations of Institution under this Agreement, notwithstanding his or her replacement hereunder.

1.3. In the event of any conflict between the terms and conditions of this Agreement and the Protocol or between this Agreement and any of its Exhibits, the terms and conditions of the Protocol shall control with respect to matters of the clinical conduct of the Study, and the terms of this Agreement shall control with respect to all other matters. Amendments or other changes to the Protocol may be made during the course of the Study ("Protocol Amendments") only by Sponsor. Any deviation from the Protocol must be pursuant to a Protocol Amendment or otherwise agreed upon in advance by Sponsor and Principal Investigator; provided, that a deviation from the Protocol will be allowed without a Protocol Amendment or such advance agreement only to the extent necessary to eliminate an apparent immediate hazard to the safety, rights or welfare of any Research Subject. In such case, Institution shall ensure that any such deviations from the Protocol will be accurately reported to Sponsor on the appropriate form within five working days of the deviation coming to notice and will be managed in full compliance with all Applicable Law or other applicable requirements.

1.4. Unless otherwise agreed to by the Parties, Sponsor will provide to Institution on a timely basis, without cost, the required quantities of properly-labeled Sponsor device(s) (the "Study Device") and other materials (e.g., Investigator's Brochure, handling and storage instructions) necessary for Institution to conduct the Study in accordance with the Protocol. Unless stated otherwise in writing by Sponsor, all such items are and will remain the sole property of Sponsor until administered or dispensed to Research Subjects during the course of the Study. Receipt, storage, and handling of Study Device will be in compliance with all Applicable Laws and regulations, the Protocol, and Sponsor's written instructions.

1.5. Sponsor, Principal Investigator, and Institution shall comply with and conduct all aspects of the Study in compliance with all applicable federal, state, and local laws and regulations, including, but not limited to, generally accepted standards of good clinical practice as adopted by current U.S. Food and Drug Administration ("FDA") regulations and statutes and regulations of the U.S. Government relating to exportation of technical data, computer software, laboratory prototypes, and other commodities as applicable to academic institutions. Institution will only allow its employees and medical staff (as applicable) ("Study Personnel") who are appropriately trained and qualified to assist in the conduct of the Study.

1.6. Institution shall obtain IRB approval for the Study and proof thereof shall be provided to Sponsor. Initiation of the Protocol and Institution's obligation to conduct the Study shall not begin until IRB approval is obtained. Prior to a Research Subject's participation in the Study, Institution shall obtain from each Research Subject, a signed informed consent in accordance with 21 CFR, Part 50, and any other applicable federal, state, and local statutes and regulations, as evidenced by each Research Subject's or legal guardian's signature on the most current consent form approved by Sponsor and the IRB (the "Informed Consent Form") and necessary HIPAA Authorization (as defined below) to disclose health information to Sponsor, provided that the Informed Consent Form is consistent with Institution's policies, or Institution shall obtain a waiver of consent as directed by the IRB. Any changes proposed by the Sponsor to the Protocol must be in writing and sent to the Institution and will not take effect until approved by the IRB. If such Protocol changes affect the contract terms (including the budget or payment terms), the Sponsor agrees to promptly work with the Institution to execute an amendment to this Agreement. If not included in the Informed Consent Form, Institution shall also secure, from each Research Subject enrolled into the Study, an authorization compliant with the Health Insurance Portability and Accountability Act of 1996, as amended and its implementing regulations ("HIPAA") to disclose Protected Health Information ("PHI") as defined in HIPAA, to Sponsor, as set forth in Sections 3.8 and 5.1 (such authorization, a "HIPAA Authorization" and such authorization form, a "HIPAA Authorization Form").

1.7. Sponsor agrees to provide Institution through Principal Investigator or designee with any data and safety monitoring reports related to the Study, and Institution agrees that such reports will be submitted to the IRB as required. During the Study and for at least two years following the completion of the Study at all sites, 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 (i) affect the safety and welfare of current or former Research Subjects, or (ii) influence the conduct of the Study. Institution and/or Principal Investigator will communicate findings to the IRB and Research Subjects, as appropriate.

1.8. The Principal Investigator shall immediately, and in any event within 48 hours, inform Sponsor and IRB of all adverse events (as set forth and defined in the Protocol, "Adverse Events") or Study-related safety issues, or breaches of the Protocol of which Institution becomes aware, including the failure to obtain the Informed Consent Form. Principal Investigator shall record Protocol deviations in the Study Records (as defined below). Institution may deviate from the Protocol to protect Research Subjects from an immediate hazard or health concern before written approval can be obtained. Any such deviation will not constitute a failure to comply with the Protocol or a breach of this Agreement. To the extent possible, Institution will use best efforts to quickly remedy violations and deviations from the Protocol. Principal Investigator will obtain and maintain in his/her files all pertinent clinical data relating to all Adverse Events, including without limitation clinical records, clinical information and clinical judgments from colleagues who assisted in the treatment and follow-up of the Research Subject. Sponsor shall promptly inform Institution in writing of any Adverse Events or other information gathered regarding the Study that may affect the safety of Research Subjects or their willingness to

continue participation in the Study, influence the conduct of the Study, or alter the IRB's approval to continue the Study.

2. Payments. Sponsor agrees to pay Institution in accordance with the budget attached as Exhibit A ("Budget") on a prorated basis, according to the actual work completed and any non-cancelable obligated expenses, for Research Subjects who are enrolled into the Study in accordance with this Agreement and the Protocol. The Parties acknowledge that the Budget amounts represent an equitable exchange for the conduct of the Study in light of the professional time and expenses required for the performance of the Study. The Parties further acknowledge that the compensation provided for in the Budget includes compensation for the assignment and other intellectual property rights provided to Sponsor under Section 8 (Inventions, Discoveries and Patents), and is inclusive of any and all applicable fees, overhead or similar charges, as well as sales and other taxes and Research Subject related costs, as applicable

In addition to other necessary routing information detailed in Exhibit A, each payment shall clearly reference the Study Protocol Number and Principal Investigator name.

Payment shall be made to "San Bernardino County on behalf of Arrowhead Regional Medical Center." The Institution's tax identification number is: 95-6002748.

3. Confidentiality

3.1. It is anticipated that in the performance of this Agreement, Sponsor may need to disclose to Institution and Principal Investigator, information which is considered confidential. The rights and obligations of the Parties with respect to such information are as follows:

"Confidential Information" refers to information of any kind which is disclosed to the Institution and/or Principal Investigator by or on behalf of Sponsor for purposes of conducting the Study and/or using, generating or otherwise acquiring Data (as defined below in Section 4 (Data Use/Ownership)) which may include information relating to such matters as product design, research and development, manufacturing methods, processes, techniques, formulations, procedures, testing methodologies, chemical composition of materials, applications for particular technologies and chemical compounds, materials or designs, customer lists, sales and marketing plans, the progress and results of the Study and all Data, reports and information developed by Institution, the Principal Investigator or any Institutional Personnel, either alone or with others, as a result of their work in connection with this Agreement, which:

(a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure;

(b) if disclosed orally or visually, is identified in a marked writing within 30 days as being confidential or verbally disclosed as confidential; or

(c) in the absence of markings, is of such a nature that a reasonable person familiar with the Study would consider it to be confidential or proprietary from the context or circumstances of disclosure.

Institution agrees, for a period of five years following either the early termination of the Study, or the completion of the Study at all sites as identified by the locking of the database, that it will use reasonable efforts, no less than the protection given to its own confidential information, to not use or disclose the Confidential Information, except as permitted under this Agreement. Furthermore, to protect Confidential Information, Institution and/or Principal Investigator agrees to: (i) limit dissemination of Confidential Information to only those employees, agents, and consultants having a "need to know"; (ii) advise each employee, agent, or consultant who receives Confidential Information of the confidential nature of such information and ensure they are bound by obligations of confidentiality and nonuse substantially similar to those of this Agreement.

Institution agrees to use Sponsor's Confidential Information solely as allowed by this Agreement, and for the purposes of conducting the Study. Institution agrees to make Sponsor's Confidential Information available only to those of its, or its affiliated hospitals' Study Personnel, and approved subcontractors, as applicable, who require access to it in the performance of this Study and the Agreement and are subject to the same or more stringent terms of confidentiality.

3.2. The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:

(a) is or becomes public knowledge through no breach of this Agreement by Institution, Principal Investigator, or Study Personnel;

(b) is disclosed to Institution by a third party entitled to disclose such information without known obligations of confidentiality.

(c) is already known or is independently developed by Institution without use of, reliance upon, or reference to, Sponsor's Confidential Information as shown by Institution's contemporaneous written records or other verifiable evidence; is necessary to obtain IRB approval of the Study or is required to be included in the written information summary provided to Research Subject(s) and/or the Informed Consent Form or the HIPAA Authorization Form; or

(d) is released with the prior written consent of the Sponsor.

3.3. Institution may disclose Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable laws, regulations, an order by a government agency, IRB, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Institution, subject to the requirement, order, or subpoena and to the extent permissible under applicable laws, promptly notifies Sponsor to enable Sponsor to limit the scope of such disclosure and/or seek to obtain a protective order. In the event that such protective order or other remedy is not obtained, Institution will disclose only the minimum amount of Confidential Information necessary to comply with Applicable Law or court order as advised by Institution's legal counsel.

3.4. No license or other right is created or granted hereby, except the specific right to conduct the Study as set forth by the Protocol and under the terms of this Agreement, nor shall

any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the Parties duly signed by their authorized representatives.

3.5. Upon Sponsor's written request, Institution agrees to return (or, at its election, destroy) all Confidential Information supplied to it by Sponsor pursuant to this Agreement except that Institution may retain one copy of such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement provided that any Confidential Information so retained shall continue to be bound by the restrictions of confidentiality and non-use set forth herein for so long as such Confidential Information is so retained. Upon request in writing by Sponsor, Institution shall certify in writing (email being sufficient) its compliance with this Section 3.5.

3.6. Institution may disclose the existence of this Agreement and any additional information necessary to ensure compliance with Applicable Laws, and Institutional policies, regulations, and procedures.

3.7. Institution acknowledges that a breach of this Agreement by it or any person to whom it discloses Confidential Information may result in irreparable and continuing damage to Sponsor, for which there may be no adequate remedy at law; and Institution agrees that, in the event of any such breach of the confidentiality-related provisions of this Agreement, Sponsor shall be entitled to seek injunctive relief and to seek such other and further relief, including damages, as may be proper.

4. Data Use/Ownership. "Data" shall mean all data and information generated, collected, or otherwise used by Institution and Study Personnel in the performance of the Study in accordance with the IRB approved Protocol. Data does not include original Research Subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in Institution's ordinary course of business operations, which shall remain the sole and exclusive property of Institution or medical provider. Sponsor shall own and have the right to use the Data in accordance with the signed Informed Consent Form and HIPAA Authorization Form, Applicable Laws, and the terms of this Agreement. Notwithstanding any licenses or other rights granted to Sponsor herein, but in accordance with Sections 3 (Confidentiality) and 9 (Publication) sections herein, Institution shall retain the right to use the Data and results for publication, IRB, regulatory, legal, and for its own internal educational, noncommercial patient care, and noncommercial research purposes, without the payment of royalties or other fees. All Data may be used by Sponsor for any lawful purpose.

5. HIPAA Privacy/Data Security

5.1. Institution shall comply with applicable federal, state and local laws and regulations, as amended from time to time, including without limitation, the Federal Food, Drug and Cosmetic Act, as amended (the "FDCA"), the current good clinical practices guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice, and applicable version(s) of the World Medical Association Declaration of Helsinki, HIPAA with respect to the collection, use, storage, and disclosure of PHI and, where applicable, rules governing, distribution practice, manufacturing practice and good laboratory practice, and rules governing

the collection and processing of personal data and the collection and storage of human tissue samples (collectively, "Applicable Laws"). Institution shall obtain valid authorizations from each Research Subject to permit the release by Institution of PHI related to the Study to Sponsor and Sponsor shall collect, use, store, access, and disclose PHI and other personal information collected from Research Subjects only as permitted by the IRB-approved Informed Consent Form or HIPAA Authorization Form obtained from a Research Subject. Sponsor will collect, use, store, and disclose any Subject Material, as defined in Section 15 (Subject Material), it receives only in accordance with the Informed Consent Form and, in any event, will not collect, use, store, or disclose any PHI attached to or contained within the Subject Material in any manner that would violate this Section 5.1 of the Agreement. Institution will comply with HIPAA in its conduct of the Study and reporting of the Data to Sponsor, and Institution shall notify Sponsor immediately in the event of any breach of data security or unauthorized access, use, or disclosure of Study-related of PHI, PII (as defined below), or Data.

5.2. Sponsor is responsible for the security of Data in its possession and shall ensure that it and any of its contractors adopt, implement and maintain appropriate security controls, including but not limited to encryption in transit, to protect against unauthorized access, use, or disclosure of any PHI or Personal Identifiable Information ("PII") of the Research Subjects or any Institution employees, agents or customers. Sponsor accepts responsibility and liability for any unauthorized disclosure by it or its contractors and shall notify Institution immediately in the event of any breach of data security or unauthorized release of PHI or PII.

5.3. Institution acknowledges that, pursuant to Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("MMSEA"), Sponsor has an obligation to submit certain reports to the Centers for Medicare & Medicaid Services ("CMS") with respect to Medicare beneficiaries who participate in the Study and experience a research injury for which diagnosis or treatment costs are incurred. Sponsor recognizes that Institution and Sponsor are subject to laws and regulations protecting the confidentiality of Research Subject information. Accordingly: (1) Institution agrees, upon prior written request, to provide to Sponsor, or a third-party vendor as designated by Sponsor, certain identifiable patient information required to be disclosed by Sponsor to CMS under MMSEA for Research Subjects who are Medicare beneficiaries and incur medical costs in association with a research injury and whose costs are reimbursed by Sponsor pursuant to this Agreement; and (2) Institution further agrees to otherwise cooperate with Sponsor (and any third-party vendors as designated by Sponsor) to the extent necessary for Sponsor to meet its MMSEA reporting obligations.

5.4. Institution agrees to allow Sponsor personnel to review the Research Subjects' Study-related information contained in the Research Subject's medical record, subject to reasonable safeguards for the protection of Research Subject confidentiality and the Research Subjects' Informed Consent Form or HIPAA Authorization Form.

5.5. Sponsor shall not attempt to identify, or contact, any Research Subject unless expressly permitted by the Informed Consent Form.

5.6. Institution shall permit regulatory authorities to audit or inspect all facilities, laboratory and clinical data and other materials relating to the Study and will cooperate with such regulatory authorities in connection with such audit or inspection. Institution shall immediately

notify Sponsor of, and provide Sponsor copies of, any inquiries, correspondence or communications to or from any regulatory authority relating to the Study, including, but not limited to, requests for inspection of Institution's facilities, and if legally permissible Institution shall permit Sponsor and its designees and their respective representatives to attend any such inspections. Whenever feasible, Institution and the Principal Investigator will also provide Sponsor with an opportunity to prospectively review and comment on any Institution responses to regulatory findings or correspondence and Institution will in good faith consider all comments from Sponsor in its response.

5.7. Institution and Sponsor shall access and use the medical records and PHI of a Research Subject only in accordance with Applicable Law, the Informed Consent Form and the HIPAA Authorization Form. All individually identifiable health information shall be treated as confidential by the Parties hereto in accordance with all Applicable Laws governing the confidentiality and privacy of individually identifiable health information, including, without limitation, HIPAA and any regulations and official guidelines promulgated thereunder. The Parties acknowledge that the Data may include PHI as that term is defined in the Privacy Rule enacted pursuant to HIPAA (the "HIPAA Privacy Rule"). Each Party will take appropriate measures to protect the confidentiality and security of all PHI that it receives in connection with the Study. Each Party shall collect, use, store, access, and disclose PHI collected from Research Subjects only as permitted by the IRB approved Informed Consent Form and HIPAA Authorization Form obtained from a Research Subject enrolled in the Study. If, in connection with the Study or the terms of this Agreement, Sponsor comes into contact with PHI relating to patients who are not Research Subjects, Sponsor agrees to promptly notify Institution of its contact with such PHI, maintain the confidentiality of such information, not to use it for any unauthorized purpose, immediately return or destroy any such PHI in its possession, and prevent further access to or disclosure of such information.

5.8. The Parties will comply with Applicable Law related to the receipt or payment of referral fees and Applicable Law related to any government-sponsored health insurance program. Accordingly, 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 and no such payments are intended to induce illegal referrals of business

5.9. In the event that any part of this Agreement is determined to violate any Applicable Law, the Parties agree to negotiate in good faith revisions to the provision or provisions which are in violation

6. Record Retention

6.1. Institution shall perform the recordkeeping and reporting obligations described in the Study Protocol and as may otherwise be required by Applicable Law ("Study Records"). All Study Records shall be complete, current, accurate, organized and legible, and will be in a form acceptable for the collection of data for submission to or review by regulatory authorities, as required by Applicable Law. Study Records include, but are not limited to, the following: (i) all correspondence pertaining to the Study; (ii) records of the disposition of the Study Device received, including dates, quantity and use by Research Subjects; (iii) case histories, which will include all observations (such case histories to be prepared and maintained in the Research

Subject's medical records); (iv) signed Inform Consent Forms and HIPAA Authorization Forms; and (v) all other data (including the Data) and records relating to the Study.

6.2. As applicable by law, Institution shall retain and preserve a copy of the Study Records for the longer of:

(a) two years after a marketing authorization for Study Device has been issued for the indication for which it was investigated under this Agreement and the Protocol or Sponsor has discontinued research on the Study Device, as confirmed in writing by Sponsor;

(b) date on which the Study is suspended, terminated or completed;

(c) such longer period as required by applicable federal or state law and regulations; or

(d) as requested in writing by Sponsor.

6.3. The Principal Investigator shall record data from each Research Subject visit on an electronic case report form ("eCRF") for the Study within 24 hours after execution of the Informed Consent Form occurs and within five business days following the date of the procedure or clinic visit by the Research Subject, as required by the Protocol. All required questions on each eCRF must be answered completely and accurately and be query-free. If a referring physician is following the Research Subject, Institution shall ensure that the Principal Investigator will coordinate data collection with the referring physician.

6.4. The Principal Investigator will complete any forms or reports requested by Sponsor and/or described in the Protocol and will do so in an accurate, complete, and timely manner. In addition, The Principal Investigator shall cause to be provided in a timely manner annual and final reports to Sponsor and the IRB, as described in the Protocol (or more frequently as requested by the IRB).

6.5. Institution shall use reasonable efforts to notify Sponsor, in writing, at least 45 days before the planned destruction of any Study records. Upon written request from Sponsor Institution shall retain the Study records for a longer period or transfer the Study records to Sponsor, provided that such written request is received within such 45 day period and that, any continued record retention or transfer of records shall be at Sponsor's sole expense. If Sponsor does not respond to Institution's notice within 45 days of its receipt or refuses to pay for the continued storage of Study records, Institution shall have the right to destroy such Study records, at its discretion.

7. Monitoring and Auditing

7.1. Site visits by Sponsor and/or its authorized designee (including, but not limited to, Study Monitor, as defined below) will be scheduled in advance for times mutually acceptable to the Parties during normal business hours. Institution shall permit Sponsor and/or its authorized designee to review personnel, procedures and facilities; discuss with Principal Investigator the general obligations regarding the Study; review the Study files, records and the forms used for data collection for completeness and adherence with the Protocol; and issue and seek responses

to questions to clarify the Data. Upon request from Sponsor, Institution will permit remote electronic access to the Data when available and permitted under Applicable Law and Institution's policies. Sponsor's and/or its authorized designee's access is subject to applicable Institution policies and procedures, including, but not limited to, reasonable safeguards to ensure confidentiality of medical records and systems.

7.2. Unless otherwise prohibited by FDA/regulatory authority, upon becoming aware of an audit, investigation or inspection related to the Study by a regulatory agency with jurisdiction over the Study, the Principal Investigator agrees to provide Sponsor with notice, and in any event no later than 48 hours, of the audit, investigation or inspection as soon as possible. Institution will cooperate with the agency conduction the audit, investigation, or inspection. Sponsor or its authorized designee may be available on site for the purposes of making itself available to assist the Institution with any queries from the regulatory authority that may require or benefit from input from the Sponsor. If required by the regulatory agency or otherwise allowed by the regulatory agency, Sponsor or its authorized designee may be present at such audit or investigation, but Sponsor agrees not to alter or interfere with any documentation or practice of Institution.

7.3. The Principal Investigator will promptly forward to Sponsor copies of any inspection findings that Institution receives from a regulatory agency in relation to the Study. Whenever possible, the Principal Investigator will also provide Sponsor with an opportunity to review and comment on any Institution responses to regulatory agency inspections in regard to the Study in advance of submission thereof. Institution shall be free to respond to any regulatory agency inquiries and will provide Sponsor with a copy of any formal response or documentation to the regulatory agency regarding the Study.

7.4. In the event Sponsor, or Sponsor's representatives, affiliates, employees, independent contractors, or subcontractors, will monitor Institution Research Subject Data ("Monitors"), Sponsor agrees that it, and its Monitors will comply with all of Institution's applicable policies and procedures related to such monitoring, provided that Sponsor and Monitors have been advised in writing of such policies and procedures prior to monitoring activities.

8. Inventions, Discoveries and Patents

8.1. It is recognized and understood that certain existing inventions and technologies, and those arising outside of the research conducted under this Agreement ("Other Inventions"), are the separate property of Sponsor or Institution and are not affected by this Agreement, and neither Sponsor nor Institution shall have any claims to or rights in such Other Inventions; provided however that if any such Other Inventions owned by Institution are necessary for the use of the Sponsor Inventions (as defined below), then Sponsor shall have, and Institution hereby grants to Sponsor, a fully-paid and royalty-free non-exclusive, irrevocable, assignable, license, with the unrestricted right to sublicense through multiple tiers, to make, use, have made, copy, modify, make derivative works of, use, offer to sell, sell, import, otherwise distribute, exploit, and exercise any and all present or future rights in such Other Inventions. Further, Institution hereby grants and agrees to grant to Sponsor an exclusive option ("Option") to obtain an exclusive, worldwide license, with the right to sublicense through multiple tiers, to make, use,

offer to sell, sell, import and otherwise exploit any Other Inventions on commercially reasonable terms. Institution agrees to promptly disclose in writing to Sponsor all Other Inventions. Sponsor shall have 90 days after Sponsor's receipt of Institution's written disclosure of an Other Invention to exercise Sponsor's Option with respect to such Other Invention.

8.2. Title to any new inventions, developments, or discoveries, concepts, ideas, know-how, innovations, or discoveries, whether patentable or not, conceived and/or reduced to practice in the performance of the Study or that use or incorporate, or enhance, modify or improve the Study Device (or any component thereof) including any use of, method of manufacturing, design, preparation, administration, method of predicting responsiveness and whether or not conceived of and/or reduced to practice by the Principal Investigator or other Institution employees or agents alone or jointly with Sponsor personnel or are otherwise based on, rely on, or reference, Confidential Information of Sponsor or arise out of or in connection with the Study shall reside with, and be owned exclusively by, Sponsor ("Sponsor Inventions"). Institution hereby assigns and agrees to assign all Sponsor Inventions to Sponsor in writing and the Principal Investigator, Study Personnel and any of Institution's employees or agents shall assign to Sponsor, all of their right, title, and interest in and to all Sponsor Inventions.

8.3. The Principal Investigator and/or Institution will disclose promptly, and in any event no later than 48 hours, to Sponsor any and all Sponsor Inventions. The Institution will execute and the Principal Investigator or Study Personnel will execute, at Sponsor's expense, any and all applications, assignments, or other instruments, give such testimony and provide such other reasonable assistance necessary to evidence, effect, perfect or record Sponsor's sole ownership of Sponsor Inventions and to apply for, secure, and maintain patent or other proprietary protection of such Sponsor Inventions worldwide. All Sponsor Inventions and any information with respect thereto shall be Confidential Information of Sponsor and subject to the continuing obligations of confidentiality and non-use set forth in Section 3 (Confidentiality) of this Agreement.

8.4. Nothing contained in this Agreement shall be deemed to grant either directly by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either Party. The Parties (including Institution, the Principal Investigator and any other Study Personnel) will cooperate with each other, and Institution will cause the Principal Investigator and other Study Personnel to cooperate with Sponsor, to take all reasonable steps to protect and perfect the rights of Sponsor and Institution in any Intellectual Property covered by the Agreement.

9. Publication

9.1. Institution and the Principal Investigator shall be free to publish, present, or use any Data and results arising out of its performance of the Protocol (individually, a "Publication") in accordance with this Section 9 of this Agreement. At least 60 days prior to submission for Publication, Institution or the Principal Investigator, as applicable, shall submit to Sponsor any proposed oral or written Publication for Sponsor's review and comments (the "Review Period"). Institution and the Principal Investigator will consider any such comments in good faith. If during the Review Period, Sponsor notifies Institution in writing that: (i) it desires to file patent applications on any inventions disclosed, described or otherwise contained in the Publication,

Institution will defer Publication for a period not to exceed 60 additional days, to permit Sponsor time to file any desired patent applications; and (ii) if the Publication contains Sponsor's Confidential Information as defined in Section 3 (Confidentiality) and Sponsor, in writing, requests Institution to delete such Sponsor's Confidential Information, then Institution agrees to do so.

9.2. If this Study is part of a multi-center clinical trial, Institution agrees that the first Publication of the results of the Study shall be made in conjunction with the presentation of a joint multi-center Publication of the Study results with the Principal Investigators from all sites contributing Data, analyses, and comments. Notwithstanding the foregoing, Institution may publish the Data and Study results individually in accordance with this Section 9 upon the first occurrence of one of the following: (i) multi-center Publication is published; (ii) no multi-center publication is submitted within 18 months after conclusion, abandonment, or termination of the Study at all sites, as confirmed in writing by Sponsor; or (iii) Sponsor confirms in writing there will be no multi-center Publication.

9.3. If no multi-center Publication occurs within 18 months of the completion of the Study at all sites, upon request by Institution, Sponsor agrees to provide Institution access to the aggregate results pursuant to the Protocol from all Study sites.

9.4. If the Institution, through its Principal Investigator, is identified to participate in the multi-center Publication: (i) Institution will have the opportunity to review the aggregate multi-center Data, upon written request; and (ii) consistent with the International Committee of Medical Journal Editors (ICMJE) regulations, Institution will have adequate opportunity to review and provide input on any abstract or manuscript prior to its submission for Publication. Institution also retains the right, on behalf of its Principal Investigator, to decline to be an author on any Publication.

10. Use of Name

10.1. Neither Institution nor Sponsor may use the name, trademark, logo, symbol, or other image or trade name of the other Party or its employees and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies endorsement without the prior written consent of an authorized representative of the Party whose name is being used. Such approval will not be unreasonably conditioned, withheld or delayed. Notwithstanding the foregoing, Sponsor understands that Institution is a public entity under California law and that it is required to comply with numerous sunshine laws, including, but not limited to the Ralph Brown Act, and that this Agreement, its purpose, and the name of Sponsor will be made public as part of a public agenda and the approval process for this Agreement under California law, and that such actions do not violation this Section 10.1.

10.2. The Parties understand that the amount of any payment made hereunder may be disclosed and made public by a Party as required by law or regulation, including the Patient Protection and Affordable Care Act of 2010 ("Disclosure Laws"), provided that the disclosure clearly indicates that the payment was made to Institution for research and not to the Principal Investigator or other physician. Institution acknowledges that, by Sponsor's disclosure of such

payments, Sponsor must identify the Institution as the payment recipient, and may also need to identify the Principal Investigator in accordance with Disclosure Laws.

10.3. Institution may acknowledge the Sponsor's support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations and agrees to comply with any such requirements. Notwithstanding anything to the contrary in this Agreement, Sponsor agrees to allow publicly registered information about the Study to appear on Institution's clinical trials directory/website. Additionally, notwithstanding anything herein to the contrary, Institution shall have the right to post Sponsor's name, the Study title, and the Study period, and funding amount, on Institution's publicly accessible lists of research conducted by the Institution.

11. Indemnification and Limitation of Liability

11.1. Sponsor shall defend, indemnify, and hold harmless Institution and its officers, employees, agents, the Principal Investigator, and all Study Personnel (collectively, "Institution Indemnitees") from and against any liability, claims, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) to a third party (each a "Loss") incurred by or imposed upon Institution Indemnitees or any one of them in connection with any third party claims, suits, actions, demands, or judgments (each, a "Claim") but only to the extent such Claim arises from or is caused by (i) the proper use and administration of the Study Device in the Study or any procedure properly performed in accordance with the Protocol; (ii) the negligence, recklessness or intentionally wrongful acts or omissions of the Sponsor; (iii) patent or other intellectual property infringement from the use of the Study Device in accordance with the Protocol; or (iv) the Sponsor's failure to comply with Applicable Law in connection with the performance of the Study or its obligations hereunder.

11.2. Sponsor shall have no obligation to provide such indemnification to the extent that such Losses arise from any Institution's Indemnitee(s)': (1) failure to adhere to and comply with this Agreement and all material and substantive specifications and directions set forth in the Protocol (except to the extent such deviation is reasonable to protect the rights, safety and welfare of the Research Subjects and Sponsor is promptly apprised of such deviation); (2) failure to comply with all Applicable Laws and regulations in the performance of the Study and its obligations hereunder, or (3) negligence, recklessness, intentionally wrongful acts or omissions, or fraud of Institution's Indemnitees.

11.3. Institution and Principal Investigator accept responsibility for, and shall not seek additional damages from Sponsor for, claims arising from Institution Indemnitees sole negligent acts or omissions or willful misconduct in the performance of the Study. For the avoidance of doubt, the parties acknowledge and agree that Institution's acceptance of responsibility shall not be deemed to be a contractual obligation to indemnify, defend, or hold harmless Sponsor, or any third party.

11.4. The indemnified Party shall give notice to the indemnifying Party promptly upon receipt of written notice of a Claim for which indemnification may be sought under this Agreement, provided, however, that failure to provide such notice shall not relieve indemnifying Party of its indemnification obligations except to the extent that the indemnifying Party's ability

to defend such Claim is materially and adversely affected by such failure. Indemnifying Party shall not make any settlement admitting fault or incur any liability on the part of the indemnified Party without indemnified Party's prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed. The indemnified Party shall cooperate with indemnifying Party in all reasonable respects regarding the defense of any such Claim, at indemnifying Party's expense. The indemnified Party shall be entitled to retain counsel of its choice at its own expense. In the event a Claim falls under this indemnification clause, in no event shall the indemnified Party compromise, settle or otherwise admit any liability with respect to any Claim without the prior written consent of the indemnifying Party, and such consent not to be unreasonably withheld, conditioned, or delayed.

11.5. EXCEPT FOR THE PARTIES' CONFIDENTIALITY OBLIGATIONS, GROSS NEGLIGENCE, WILLFUL BREACH, FRAUD AND INDEMNITY OBLIGATIONS, NEITHER PARTY SHALL BE LIABLE FOR PUNITIVE, SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME AND WHETHER SUCH CLAIM IS BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, EVEN IF AN AUTHORIZED REPRESENTATIVE OF THE PARTY, AS APPLICABLE, IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

11.6. SPONSOR MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY OF THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT REGARDING THE STUDY DEVICE, CONFIDENTIAL INFORMATION OR ANY OTHER SUBJECT MATTER OF THIS AGREEMENT. ADDITIONALLY, SPONSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, REGARDING THE SAFETY OR EFFICACY OF THE STUDY DEVICE.

12. Subject Injury. The Principal Investigator shall promptly notify Sponsor if a Research Subject suffers an adverse reaction, medical illness, or injury which was directly caused by a Study Device and/or any properly performed procedures required by the Protocol, and Sponsor shall reimburse for the reasonable and necessary medical costs not otherwise covered by patient insurance or government programs for any Research Subject injury, including hospitalization, but only to the extent such adverse reaction, medical illness or injury are not directly caused by (i) the negligence or willful misconduct of Institution, Principal Investigator, or Study Personnel; (ii) the natural progression of an underlying or pre-existing condition or events, unless exacerbated by participating in the Study; or (iii) Institution's failure to adhere to and comply with the specifications of the Protocol and all reasonable written instructions furnished by Sponsor for the use and administration of any Study Device used in the Study, provided that deviations from the Protocol and written instructions resulting from an imminent threat to the health or safety of a Research Subject that do not cause the injury to the Research Subject will not disqualify Institution from reimbursement under this provision. The Principal Investigator and/or Institution and Sponsor agree that terms substantially similar to this Section 12 will appear in the Research Subjects' Informed Consent Form and that Institution and/or Principal Investigator and Sponsor will perform according to these terms. Institution

acknowledges that Sponsor must report certain information to CMS with respect to Medicare beneficiaries who participate in the Study and experience a research injury for which diagnosis or treatment costs are incurred and agrees to assist Sponsor in meeting Sponsor's reporting obligations, as set forth in Section 5.3 (HIPAA Privacy/Data Security) above.

13. Insurance

13.1. Institution shall, at its sole cost and expense, procure and maintain a policy of insurance at a level to support its obligations assumed in this Agreement, and nevertheless at a level of at least $1,000,000 per occurrence (or per claim) and $3,000,000 annual aggregate. Institution may comply with this requirement with a program of self-insurance or otherwise per applicable law. If Institution is a public entity entitled to governmental immunity protections under applicable law, then Institution may provide liability coverage in accordance with any limitations associated with such applicable law.

13.2. Sponsor shall, at its sole cost and expense, procure and maintain a policy of insurance at a level to support its obligations assumed in this Agreement and in as may be specified in Exhibit C, attached hereto and incorporated herein by this reference.

13.3. Upon written request, either Party will provide evidence of its insurance acceptable to the other Party. A Party's inability to meet its insurance obligation constitutes material breach of this Agreement. Either Party will provide the other Party with written notice of material change in its coverage which would affect such Party's ability to meet its obligations under this Agreement.

14. Term and Termination

14.1. The term of this Agreement shall commence upon the Effective Date and terminate upon the completion of the Parties' Study-related activities under the Agreement, unless terminated earlier as further described in this Section 14.

14.2. Sponsor has the right to terminate the Study upon 30 days prior written notice to the Institution. This Study may be terminated immediately upon written notice to the other Party by either the Institution or Sponsor when, in its judgment or that of the Principal Investigator, the Institution's IRB, Scientific Review Committee, if applicable, or the FDA, it is determined that termination is necessary in order to protect the Research Subjects' rights, welfare, and safety, or the IRB otherwise disapproves the Study. If for any reason Principal Investigator becomes unavailable to direct the performance of the work under this Agreement, Institution shall notify Sponsor. Any successor Principal Investigator shall sign a counterpart signature page hereto acknowledging receipt of the terms and provisions of this Agreement, whereupon such successor Principal Investigator shall thereafter be deemed to be the Principal Investigator under this Agreement for all purposes. If the Parties are unable to identify a mutually acceptable successor Principal Investigator, this Agreement may be terminated by either Party upon 30 days written notice.

14.3. Notwithstanding the above, any Party may, in addition to any other available remedies:

(a) immediately terminate this Agreement upon the other Party's material failure to adhere to the Protocol, except for deviation required to protect the rights, safety, and welfare of Research Subjects; and/or

(b) terminate this Agreement upon the other Party's material default or breach of this Agreement, provided that prompt written notice of such default or breach is given to the defaulting/breaching Party and such Party fails to remedy such material default or breach within 30 business days after written notice thereof; or

(c) immediately upon mutual agreement between Sponsor and Institution.

(d) terminate this Agreement for convenience with at least 90 days prior written notice to the other Party.

14.4. In the event that this Agreement or the Study is terminated for any reason prior to completion of the Study, Institution and/or Principal Investigator shall:

(a) notify the IRB that the Study has been terminated;

(b) cease enrolling Research Subjects in the Study;

(c) cease treating Research Subjects under the Protocol as directed by Sponsor to the extent medically permissible and appropriate;

(d) terminate, as soon as practicable, all other Study activities in accordance with the Protocol; and

(e) furnish to Sponsor any required final report for the Study in the form reasonably acceptable to Sponsor.

Promptly following any such termination, Institution and/or Principal Investigator will provide Sponsor copies of Data collected pursuant to the Study Protocol. Upon Sponsor's written request, Institution agrees to return all Confidential Information supplied to it by Sponsor, at Sponsor's expense, pursuant to this Agreement except that Institution may retain such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement, provided that Institution continues to comply with the confidentiality requirements set forth in Section 3 (Confidentiality) of this Agreement.

14.5. If this Study is terminated early by either Party, the Institution shall be reimbursed for all work completed, on a pro rata basis, and reasonable costs of bringing the Study to termination incurred through the date of termination, and for non-cancelable commitments properly incurred prior to the date on which notice of termination was received. Upon receipt of notice of termination, Institution will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with Sponsor to provide for an orderly wind-down of the Study.

14.6. Subsections 1.5 (Scope of Agreement), 1.8 (Scope of Agreement), and this 14.6, and Section 2 (Payments) through Section 13 (Insurance), Section 15 (Subject Material), Section 18 (Notice), Section 20 (Clinical Trial Registry), Section 21 (Non-Referral/Anti-Corruption Language), Section 24 (Qualification of Institution and Study Personnel), Section 25 (Choice of Law), and Sections 26 through 30, shall survive any termination or expiration of this Agreement, except that Section 3 (Confidentiality) shall survive for the period stated in Section 3.1. Any provision of this Agreement that by its nature and intent remains valid after termination will survive termination.

15. Subject Material

15.1. Subject Material means any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Research Subjects as required by the Protocol ("Subject Material").

15.2. Institution agrees to make the Subject Material available to the Sponsor in accordance with the Protocol for the purposes of the Study. The Subject Material may be used by the Sponsor, central lab, or other contracted party only as allowed by the Research Subject's Informed Consent Form and/or HIPAA Authorization Form. Sponsor agrees that any use of Subject Material, other than as allowed by the Research Subject's Informed Consent Form and/or HIPAA Authorization Form, will require additional IRB review and approval.

16. Sponsor Equipment. Sponsor may, at no-cost to Institution, provide equipment for the conduct of the Study as specified by the Protocol and described in Exhibit B ("Equipment"). Institution agrees that such Equipment shall be used solely in connection with the Study during the term of this Agreement, unless the Parties have a separate written agreement that states otherwise.

17. Subcontract/Assignment

17.1. This Agreement is strictly personal to the Parties and Parties shall not assign, subcontract or delegate this Agreement or their respective rights and obligations, including those of the Principal Investigator and Study Personnel, hereunder, in whole or in part, without the prior written consent of the other Party.

17.2. The Sponsor has the right to subcontract to a third-party Contract Research Organization ("CRO") or Academic Research Organization ("ARO") and assign Study-related duties and rights to any Sponsor affiliate or third-party contractors. If Sponsor subcontracts any Study-related duties and rights, Sponsor remains responsible for any of those duties and rights. Sponsor agrees to provide Institution with prompt, written notice of any assignment and/or subcontracting in accordance with the notice requirements under this Agreement.

17.3. No assignment and/or subcontracting shall relieve either Party of the performance of any accrued obligation that such Party may have under this Agreement.

18. Notices. Any notice, authorization, approval, consent or other communication will be in writing and deemed given:

(a) Upon delivery in person;

(b) Upon delivery by courier; or

(c) Upon delivery date by a nationally-recognized overnight delivery service such as FedEx.

If to Sponsor:
Aveera Medical, Inc.
Heather White
929 Calle Negocio, Suite A
San Clemente, CA 92673
805-90-5151
hwhite@aveeramedical.com

If to Institution:
Arrowhead Regional Medical Center
400 N. Pepper Avenue
Colton, CA 92324
Attn: ARMC Chief Executive Officer

With a copy to Principal Investigator:
Samuel Schwartz, MD, FACS
1281 West C Street, 2nd Floor
Colton, CA 92324
909-747-0371
schwartzs@calmeddocs.com

19. Independent Contractor. It is mutually understood and agreed that the relationship between Parties is that of independent contractors. Neither Party is the agent, employee, partner, joint venturer, or servant of the other. Except as specifically set forth herein, neither Party shall have nor exercise any control or direction over the methods by which the other Party performs work or obligations under this Agreement. Further, nothing in this Agreement is intended to create any partnership, joint ventures, lease, or equity relationship, expressly or by implication, between the Parties.

20. Clinical Trial Registry. Prior to enrollment of the first Research Subject in the Study, Sponsor agrees to ensure that the Study is fully registered on www.clinicaltrials.gov in accordance with the requirements of the International Committee of Medical Journal Editors ("ICMJE") and 42 USC § 282 as amended and any applicable regulations including 42 CFR Part 11. Results of the Study will be reported in compliance with Applicable Laws.

21. Non-Referral/Anti-Corruption Language

21.1. The Parties to this Agreement specifically intend to comply with all Applicable Laws, rules, and regulations, including (i) the federal anti-kickback statute (42 U.S.C. 1320a-

7b(b)) and the related safe harbor regulations; and (ii) the limitation on certain physician referrals, also referred to as the "Stark Law" (42 U.S.C. 1395nn). The Parties agree that it is not their intent under this Agreement to induce or encourage the unlawful referral of Research Subjects or business between the Parties, and there shall not be any requirement under this Agreement that either Party, its employees or affiliates, including its medical staff, engage in any unlawful referral of Research Subjects to, or order or purchase products or services from, the other Party.

21.2. Each Party shall require that its employees, who are involved in the conduct of the Study, will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and shall not make or cause another to make any offer or payment to any individual or entity for the purpose of influencing a decision for the benefit of the other Party.

22. Force Majeure. If either Party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such Party's direct control that renders such Party's performance impossible or illegal, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather, or other reason beyond the Party's control (a "Disability") then such Party's performance shall be excused for the period of the Disability. Any Study timelines affected by a Disability shall be extended for a period equal to the delay and any affected Budget shall be adjusted to account for cost increases or decreases resulting from the Disability. The Party affected by the Disability shall notify the other Party of such Disability as provided for herein.

23. Counterparts. This Agreement may be executed in separate counterparts, each of which shall be an original and all of which, taken together, shall constitute one and the same agreement. Counterparts may be delivered via electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

24. Qualification of Institution and Study Personnel.

24.1. Institution certifies, to the best of its knowledge, that neither it, nor any of Study Personnel are or will be under any conflicting obligation or legal impediments that will materially interfere with the performance of the obligations of Institution under this Agreement. Institution further certifies that Institution and the Study Personnel have and will maintain throughout the Study all training, licenses, approvals, certifications, equipment and information necessary for safely and properly conducting the Study in accordance with the Protocol.

24.2. The Institution certifies that to its knowledge, after due inquiry, neither Institution, Principal Investigator, nor any of Institution's directors, officers, employees, consultants, agents or other persons involved in the Study, is currently or has previously been debarred, suspended, or excluded under the FDCA; disqualified under the provisions of 21 CFR § 312.70; excluded from participating in a federal health care program, including without limitation the Medicare or Medicaid programs; or been subject to similar actions from any other applicable regulatory agency or body. Upon written request of Sponsor, Institution shall, within

10 days, provide written confirmation that the foregoing certifications remain accurate. In the event that Institution, Principal Investigator, any of Institution's directors, officers, employees, consultants, or agents, or any personnel reported on FDA Form 1572 or its equivalent, becomes debarred, suspended, or excluded under the FDCA; disqualified under the provisions of 21 CFR § 312.70; excluded from participating in a federal health care program, including without limitation the Medicare or Medicaid programs; or subject to similar actions from any other applicable regulatory agency or body during the term of this Agreement or within 1 year after termination of the Study, Institution agrees to promptly, and in any event within 48 hours, notify Sponsor after learning of such event.

Sponsor represents and warrants that it is not and at no time has been convicted of any criminal offense related to health care nor has been debarred, excluded, or otherwise ineligible for participation in any federal or state government health care program, including Medicare and Medicaid. Further, Sponsor represents and warrants that no proceedings or investigations are currently pending or to Sponsor's knowledge threatened by any federal or state agency seeking to exclude Sponsor from such programs or to sanction Sponsor for any violation of any rule or regulation of such programs.

25. Choice of Law/Venue. This Agreement will be governed by and construed according to the laws of the State of California, excluding its conflicts of laws principles. Prior to initiating any litigation with respect to any dispute arising hereunder, the Parties will endeavor to amicably resolve such dispute. Any action arising under this Agreement shall be venued in the state or federal courts of California.

26. Entire Agreement. Section and clause headings are used herein solely for convenience of reference and are not intended as substantive parts of the Parties' agreement. This Agreement incorporates the Exhibits referenced herein. This written Agreement constitutes the entire agreement between the Parties concerning the subject matter, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter. Any changes made to the terms, conditions or amounts cited in this Agreement require the written approval of each Party's authorized representative, except that either Party may change its general contact information (e.g. mailing address) or payee information by providing written notice (including by email) to the other Party.

27. Waivers and Amendments. This Agreement will not be amended or modified nor may any of its terms be waived except in a writing signed by Sponsor and Institution. The waiver by any Party of a breach of any provisions of this Agreement will not operate or be construed as a waiver of any other breach.

28. Severability. If any provision of the Agreement is held unlawful or unenforceable in any respect, such illegality or unenforceability will not affect any other provision hereof and the remaining provisions of this Agreement will be construed as if the unlawful or unenforceable provision had never been contained herein.

29. Assignment. This Agreement will be binding upon and will inure to the benefit of the successors, assigns, and personal representatives of the Parties hereto; provided, however, the rights and obligations of either party hereunder will not be assignable without the prior written

consent of the other party. Any attempted assignment in violation of this Section 29 will be null and void.

30. Attorney's Fees and Costs. If any legal action is instituted to enforce any Party's rights hereunder, each Party shall bear its own costs and attorney's fees, regardless of who is the prevailing party. This paragraph shall not apply to those costs and attorney's fees directly arising from a third-party legal action against a Party hereto and payable as an indemnification obligation.

31. Levine Act - Campaign Contribution Disclosure (formerly referred to as Senate Bill 1439). Sponsor has disclosed to Institution using Exhibit D – Levine Act - Campaign Contribution Disclosure (formerly referred to as Senate Bill 1439), whether it has made any campaign contributions of more than $500 to any member of the San Bernardino County ("County") Board of Supervisors or other County elected officer [Sheriff, Assessor-Recorder-Clerk, Auditor-Controller/Treasurer/Tax Collector and the District Attorney] within the 12 months before the date this Agreement was approved by the County Board of Supervisors. Sponsor acknowledges that under Government Code section 84308, Sponsor is prohibited from making campaign contributions of more than $500 to any member of the Board of Supervisors or other County elected officer for 12 months after the County's consideration of the Agreement.

In the event of a proposed amendment to this Agreement, the Sponsor will provide the County a written statement disclosing any campaign contribution(s) of more than $500 to any member of the Board of Supervisors or other County elected officer within the preceding 12 months of the date of the proposed amendment.

Campaign contributions include those made by any agent/person/entity on behalf of the Sponsor or by a parent, subsidiary or otherwise related business entity of Sponsor.

[SIGNATURE PAGE FOLLOWS]

The authorized representatives of the Parties have signed this Agreement as set forth below.

SAN BERNARDINO COUNTY on behalf of Arrowhead Regional Medical Center

By: _____
Dawn Rowe

Title: Chair, Board of Supervisors

Date: _____

AVEERA MEDICAL, INC.

By: _____
Brian Driscoll

Title: President

Date: _____

SAMUEL SCHWARTZ

By: _____
Title: Principal Investigator

Date: _____

EXHIBIT A

Budget

Administrative Fees	**Description**	**Fee**
Initial IRB Submission	IRB Fee	$2250.00
IRB Amendment Review	Annually, Including Coordinator Fee	$500.00
Administrative Fee	Including Contract Fee/Coordinator Fee	$1,500.00
Trial Start Up Fee	Study Start Up (One-Time fee)	$1,500.00
Trial Close Out Fee	Study Close Out (One-Time Fee)	$1,500.00
Visit 1: Screening	**Description**	**Fee**
Informed Consent	Completion of CD-0004 - Informed Consent Form	$200.00
Inclusion / Exclusion CRF	Completion of CD-0015 - Inclusion and Exclusion Criteria for Boomerang Catheter IDE Study, Protocol 24-01	$200.00
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Rutherford Class CRF	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
VascuQoL-6	Completion of CD-0021 - VascuQoL-6 CRF	$50.00
	Total for Visit 1	**$750.00**
Visit 2: Index Procedure		
Device Accountability Form CRF	Completion of CD-0038, Device Accountability CRF	$50.00
Post-Procedure Ultrasound CRF	Completion of CD-0013	$100.00
Angiographic Evaluation of DVA Circuit CRF	Completion of CD-0014	$100.00
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
	Total for Visit 2	**$450.00**
Visit 3: One Week Post-Procedure		
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
	Total for Visit 3	**$300.00**
Visit 4: One Month Post-Procedure		
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00

Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
VascuQoL-6	Completion of CD-0021 - VascuQoL-6 CRF	$50.00
	Total for Visit 4	**$350.00**
Visit 5: Two Months Post-Procedure		
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Research: Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
Imaging: Lower Extremity Artery Duplex Ultrasound - Unilateral		$150.00
Imaging: Lower Extremity Vein Duplex Ultrasound - Unilateral		$150.00
	Total for Visit 5	**$600.00**
Visit 6: Three Months Post-Procedure		
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
VascuQoL-6	Completion of CD-0021 - VascuQoL-6 CRF	$50.00
	Total for Visit 6	**$350.00**
Visit 7: Six Months Post-Procedure		
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
VascuQoL-6	Completion of CD-0021 - VascuQoL-6 CRF	$50.00
	Total for Visit 7	**$350.00**
Visit 8: Nine Months Post-Procedure		
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
VascuQoL-6	Completion of CD-0021 - VascuQoL-6 CRF	$50.00
	Total for Visit 8	**$350.00**
Visit 9: One Year Post-Procedure		

Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
VascuQoL-6	Completion of CD-0021 - VascuQoL-6 CRF	$50.00
	Total for Visit 9	**$350.00**
Visit 10: Two Year Post-Procedure		
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
VascuQoL-6	Completion of CD-0021 - VascuQoL-6 CRF	$50.00
	Total for Visit 10	**$350.00**
Visit 11: Three Year Post-Procedure		
Wound Assessment via eKare + WiFi scoring	Use of provided eKare Phone/iPAD system to capture accurate wound images and grade WiFi score	$200.00
Rutherford Class Evaluation	Completion of CD-0006 - Rutherford Evaluation CRF	$100.00
VascuQoL-6	Completion of CD-0021 - VascuQoL-6 CRF	$50.00
	Total for Visit 11	**$350.00**

EXHIBIT B

Equipment

BMG050 – Boomerang Catheter

BMG100 – Boomerang Power Controller

BMG013-300DT – Boomerang Wire (.013" x 300cm)

BMGVT080 – Boomerang Valvulotome

BMGPVT125 – Boomerang Push Valvulotome

EXHIBIT C
Insurance Requirements

Sponsor agrees to provide insurance at a level to support its obligations assumed in this Agreement.

1. Without in anyway affecting any indemnity obligations provided and in addition thereto, Sponsor shall secure and maintain throughout the contract term the following types of insurance with limits as shown:

    a. Workers' Compensation/Employer's Liability – A program of Workers' Compensation insurance or a state-approved, self-insurance program in an amount and form to meet all applicable requirements of the Labor Code of the State of California, including Employer's Liability with $250,000 limits covering all persons including volunteers providing services on behalf of Sponsor and all risks to such persons under this contract. If Sponsor has no employees, it may certify or warrant to Institution that it does not currently have any employees or individuals who are defined as "employees" under the Labor Code and the requirement for Workers' Compensation coverage will be waived by Institution's Director of Risk Management. With respect to contractors that are non-profit corporations organized under California or Federal law, volunteers for such entities are required to be covered by Workers' Compensation insurance.

    b. Commercial/General Liability Insurance – Sponsor shall carry General Liability Insurance covering all operations performed by or on behalf of Sponsor providing coverage for bodily injury and property damage with a combined single limit of not less than one million dollars ($1,000,000), per occurrence. The policy coverage shall include:
        i. Premises operations and mobile equipment.
        ii. Products and completed operations.
        iii. Broad form property damage (including completed operations).
        iv. Explosion, collapse and underground hazards.
        v. Personal injury.
        vi. Contractual liability.
        vii. $2,000,000 general aggregate limit.

    c. Umbrella Liability Insurance – An umbrella (over primary) or excess policy may be used to comply with limits or other primary coverage requirements. When used, the umbrella policy shall apply to bodily injury/property damage, personal injury/advertising injury and shall include a "dropdown" provision providing primary coverage for any liability not covered by the primary policy.

    d. Cyber Liability Insurance - Cyber Liability Insurance with limits of no less than $1,000,000 for each occurrence or event with an annual aggregate of $2,000,000 covering privacy violations, information theft, damage to or destruction of electronic information, intentional and/or unintentional release of private information, alteration of electronic information, extortion and network security. The policy shall protect the involved Institution and cover breach response cost as well as regulatory fines and penalties.

2. **Proof of Coverage**. Sponsor shall furnish Certificates of Insurance to Arrowhead Regional Medical Center evidencing the insurance coverage at the time the Contract is executed, additional endorsements, as required shall be provided prior to the commencement of performance of services hereunder, which certificates shall provide that such insurance shall not be terminated or expire without thirty (30) days written notice to Arrowhead Regional Medical Center, and Sponsor shall maintain such insurance from the time Sponsor commences performance of services hereunder until the completion of such services. Within fifteen (15) days of the commencement of this contract, upon request, Sponsor shall furnish a copy of the Declaration page for all applicable policies and will provide complete certified copies of the policies and endorsements immediately upon request.

3. **Additional Insured**. All policies, except for Worker's Compensation, Errors and Omissions and Professional Liability policies shall contain additional endorsements naming Institution and its officers, employees, agents and volunteers as additional named insured with respect to liabilities arising out of the performance of services hereunder. The additional insured endorsements shall not limit the scope of coverage for Institution to vicarious liability but shall allow coverage for Institution to the full extent provided by the policy. Such additional insured coverage shall be at least as broad as Additional Insured (Form B) endorsement form ISO, CG 2010.11 85.

4. **Acceptability of Insurance Carrier**. Unless otherwise approved by Risk Management, insurance shall be written by insurers authorized to do business in the State of California and with a minimum "Best" Insurance Guide rating of "A- VII".

5. **Policies Primary and Non-Contributory**. All policies required herein are to be primary and non-contributory with any insurance or self-insurance programs carried or administered by Institution.

Exhibit D

LEVINE ACT – CAMPAIGN CONTRIBUTION DISCLOSURE

(FORMERLY REFERRED TO AS SENATE BILL 1439)

The following is a list of items that are not covered by the Levine Act. A Campaign Contribution Disclosure Form will not be required for the following:

- Contracts that are competitively bid and awarded as required by law or County policy
- Contracts with labor unions regarding employee salaries and benefits
- Personal employment contracts
- Contracts under $50,000
- Contracts where no party receives financial compensation
- Contracts between two or more public agencies
- The review or renewal of development agreements unless there is a material modification or amendment to the agreement
- The review or renewal of competitively bid contracts unless there is a material modification or amendment to the agreement that is worth more than 10% of the value of the contract or $50,000, whichever is less
- Any modification or amendment to a matter listed above, except for competitively bid contracts.

DEFINITIONS

Actively supporting or opposing the matter: (a) Communicate directly with a member of the Board of Supervisors or other County elected officer [Sheriff, Assessor-Recorder-Clerk, District Attorney, Auditor-Controller/Treasurer/Tax Collector] for the purpose of influencing the decision on the matter; or (b) testifies or makes an oral statement before the County in a proceeding on the matter for the purpose of influencing the County's decision on the matter; or (c) communicates with County employees, for the purpose of influencing the County's decision on the matter; or (d) when the person/company's agent lobbies in person, testifies in person or otherwise communicates with the Board or County employees for purposes of influencing the County's decision in a matter.

Agent: A third-party individual or firm who, for compensation, is representing a party or a participant in the matter submitted to the Board of Supervisors. If an agent is an employee or member of a third-party law, architectural, engineering or consulting firm, or a similar entity, both the entity and the individual are considered agents.

Otherwise related entity: An otherwise related entity is any for-profit organization/company which does not have a parent-subsidiary relationship but meets one of the following criteria:

(1) One business entity has a controlling ownership interest in the other business entity;
(2) there is shared management and control between the entities; or
(3) a controlling owner (50% or greater interest as a shareholder or as a general partner) in one entity also is a controlling owner in the other entity.

For purposes of (2), "shared management and control" can be found when the same person or substantially the same persons own and manage the two entities; there are common or commingled

funds or assets; the business entities share the use of the same offices or employees, or otherwise share activities, resources or personnel on a regular basis; or there is otherwise a regular and close working relationship between the entities.

Parent-Subsidiary Relationship: A parent-subsidiary relationship exists when one corporation has more than 50 percent of the voting power of another corporation.

Contractors must respond to the questions on the following page. All references to "Contractor" on this Exhibit refer to Sponsor. If a question does not apply respond N/A or Not Applicable.

1. Name of Contractor: Aveera Medical

2. Is the entity listed in Question No.1 a nonprofit organization under Internal Revenue Code section 501(c)(3)?

   Yes ☐ If yes, skip Question Nos. 3-4 and go to Question No. 5 No X

3. Name of Principal (i.e., CEO/President) of entity listed in Question No. 1, if the individual actively supports the matter and has a financial interest in the decision:

   _____

4. If the entity identified in Question No.1 is a corporation held by 35 or less shareholders, and not publicly traded ("closed corporation"), identify the major shareholder(s):

   _____

5. Name of any parent, subsidiary, or otherwise related entity for the entity listed in Question No. 1 (see definitions above):

Company Name	Relationship
N/A	

6. Name of agent(s) of Contractor:

Company Name	Agent(s)	Date Agent Retained (if less than 12 months prior)
Aveera Medical	Joseph Steele, MD	
Aveera Medical	Brian Driscoll	

7. Name of Subcontractor(s) (including Principal and Agent(s)) that will be providing services/work under the awarded contract if the subcontractor (1) actively supports the matter and (2) has a financial interest in the decision and (3) will be possibly identified in the contract with the County or board governed special district.

Company Name	Subcontractor(s):	Principal and//or Agent(s):

8. Name of any known individuals/companies who are not listed in Questions 1-7, but who may (1) actively support or oppose the matter submitted to the Board and (2) have a financial interest in the outcome of the decision:

Company Name	Individual(s) Name

9. Was a campaign contribution, of more than $500, made to any member of the San Bernardino County Board of Supervisors or other County elected officer within the prior 12 months, by any of the individuals or entities listed in Question Nos. 1-8?

   No X If **no**, please skip Question No. 10.

   Yes ☐ If **yes**, please continue to complete this form.

10. Name of Board of Supervisor Member or other County elected officer: _____

    Name of Contributor: _____

    Date(s) of Contribution(s): _____

    Amount(s): _____

    Please add an additional sheet(s) to identify additional Board Members or other County elected officers to whom anyone listed made campaign contributions.

By signing the Agreement, Contractor certifies that the statements made herein are true and correct. Contractor understands that the individuals and entities listed in Question Nos. 1-8 are prohibited from making campaign contributions of more than $500 to any member of the Board of Supervisors or other County elected officer while award of this Agreement is being considered and for 12 months after a final decision by the County.