

CLINICAL REGISTRY STUDY / CLINICAL TRIAL AGREEMENT

This **CLINICAL REGISTRY STUDY AGREEMENT** (the "Agreement") is made as of this 22nd day of January, 2019 (the "Effective Date") by and between XXXXXXXXXXXX (hereinafter "Institution or Clinic"), as represented by XXXXXXXXXXXX (hereinafter "Principal Investigator"), and **Leonhardt's Launchpads Utah, Inc.** a Utah corporation (hereinafter "Sponsor") with reference to the facts set forth in the Recitals below.

The parties desire to conduct a clinical registry study ("Trial or Clinical Trial") to gather information regarding the performance of cosmetic regeneration products and any related accessories, components, instruments and software ("Device(s)") according to the applicable organ specific clinical protocols for hair, skin, ED, testosterone management, joints, vaginal rejuvenation, as modified from time to time (the "Protocol(s)") (See **Appendix A for Organ Specific Protocols**). These organ specific clinical registry studies are of mutual interest and benefit to the parties because it furthers instructional and research objectives and may benefit patient care.

Institution agrees to the following:

1. Clinic will gain signed patient consent forms from all patients being treated being sure to fairly and fully apprise them of associated risks.
2. Clinic will gather all data required by the protocols and provide it to the sponsor in a prompt manner.
3. Clinic will promptly report any and all adverse events and will stop enrolling patients until adverse event investigation has been performed and renewed enrollment has been cleared.
4. Clinic will seek prior permission for any protocol deviations and will report all protocol deviations promptly and completely.
5. Clinic investigators will stay within the bounds of regulatory 510K cleared indications of use and labelling for bioelectric stimulation products studied = improving blood circulation, mild pain relief, improving motion and accelerated healing.
6. Clinic will strictly follow the protocol(s) for each application of use.
7. Company reserves right to halt clinical registry study enrollment at site immediately upon email notice at its discretion and judgement for any reason.
8. Any IP you develop independently on your own belongs to you. Any IP we develop belongs to us. Any IP developed during this study as a direct link result byproduct of the protocol and products we have provided for the study belongs to us.
9. Clinic will comply with all HIPAA regulations related to patient information confidentiality and privacy - <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>
10. Clinic and Sponsor will comply with the provisions of the Sunshine Act regarding financial conflicts of interest - <https://www.ama-assn.org/practice-management/medicare/physician-financial-transparency-reports-sunshine-act>
11. This agreement will be governed by the laws of the State of Utah. Any arbitration or court cases emanating from this work will be in Salt Lake City, Utah.

RECITALS

A. Institution is located in Salt Lake City, Utah and operates a clinic specializing in, among other things, stem cell, PRP, microneedling, microcurrent and other regenerative procedures (the "clinic"). Institution regularly performs clinical evaluations and studies for medical devices and biologics, both physician sponsored and those on behalf of external sponsors, in the clinic.

B. Sponsor desires to evaluate a full line up of bioelectric stimulation medical devices and biologics (PRF and amnio fluid derived exosomes) as a combination therapy under the brand names HairCell, SkinStim, MyoStim ED Erectistim, TestiStim, Wave, Peach, Stem Cell Bra, OrthoStim and Vascustim ("System") intended specific organ regeneration or recovery.

C. Sponsor intends to conduct a necessary clinical registry study (the "Clinical Trial or Clinical Registry Study") with the Institution, in accordance with the Protocol(s) – see Appendix for organ specific protocols ie; Hair, Skin, Breasts, Penis, Testicles, Female Internal Organs. The objective of the Clinical Registry Study is to evaluate the initial safety and device performance in up to 30 patients each undergoing hair, skin, vaginal, penis, testicles, endometriosis or breast healing, regeneration or recovery.

D. The Institution has the expertise, experience, facilities, equipment and suitable patient population necessary to carry out the Clinical Registry Study Trial Protocol, and desires to participate in the Clinical Registry Study/Clinical Trial.

E. The Principal Investigator has the expertise, experience, and standing to represent the Institution and act as its principal investigator in the conduct of the Clinical Trial, and desires to participate in the Clinical Registry Study/Clinical Trial.

F. The parties are executing this Agreement to memorialize their understanding regarding the foregoing.

AGREEMENT

NOW, THEREFORE, in consideration of the above Recitals the mutual promises in this Agreement, and other good and valuable consideration, the receipt and legal sufficiency of which are hereby acknowledged, the parties agree as follows:

1. **SCOPE AND OBJECTIVES.** The objective of the Clinical Registry Study is to evaluate the initial safety and effectiveness of the System(s) in a manner consistent with this Agreement, the Trial Protocol and requirements of applicable law and regulation. The scope of the Clinical Registry Study is stated in the organ specific Trial Protocol(s)

2. INSTITUTION AND PRINCIPAL INVESTIGATOR OBLIGATIONS.

2.1 **CONDUCT OF CLINICAL REGISTRY STUDY "CLINICAL TRIAL" AT CLINIC** Institution and Principal Investigator shall conduct the Trial in accordance with the terms and conditions of this Agreement, the Trial Protocol, applicable federal, state, and local laws. Institution and Principal Investigator shall permit the use of the System only on Patient Participants under the personal supervision of Principal Investigator or Co-

Investigators. However, it shall in no event be deemed a breach of the preceding statement if the Principal Investigator or a member of the study team shall deviate from the terms of the Trial Protocol in order to protect patient safety. Immediately upon execution of this Agreement,

2.2 INTERFACING WITH INVESTIGATORS AND MONITOR. Principal Investigator shall keep the Sponsor or Study Monitor (Monitor) at all times apprised of the status of the Clinical Trial and all material circumstances regarding the Clinical Trial and each Patient Participant. Any serious adverse events must be reported immediately by calling or texting 954 401 0096 Howard J. Leonhardt and Dr. Leslie Miller Chief Medical Officer at 813 476 3933. Any non-serious adverse events must be reported promptly via the reporting forms found within the clinical protocol and by email to Dr. Leslie Miller at lmiller1429@gmail.com

12. 2.3 INFORMED CONSENT. Prior to enrolling any patient in the Trial, the applicable Ethics Committee (the "EC") shall have approved in writing the terms and conditions of the Trial, including the Informed Consent; related instructions for use; the Protocol; and the participation of the Institution and Principal Investigator in the trial. The Principal Investigator shall obtain the Sponsor's and EC's written approval prior to using the original Informed Consent and prior to implementing any modifications. Clinic will comply with all HIPAA regulations related to patient information confidentiality and privacy - <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>

2.4 CASE REPORT FORMS. Institution and Principal Investigator shall provide to the Sponsor and/or Monitor a case report form ("CRF" or "CRFs"), on each Patient Participant treated at Institution within the Clinical Trial. Each CRF shall include all information as provided in the Trial Protocol. Principal Investigator agrees to complete, sign and deliver to the Monitor all CRFs and other information as provided in the Trial Protocol in a timely manner and shall promptly respond to requests for missing or additional patient information from either the Sponsor or Monitor.

2.5 INVESTIGATIONAL DEVICE STORAGE AND RECORD KEEPING. The Institution and Principal Investigator shall provide appropriately secured storage for all investigational clinical supplies provided by the Sponsor or Sponsor's agents, and shall maintain a device inventory indicating, by dates and numbers, investigational devices, including any sub-components, received from Sponsor or Sponsor's agents, the Patient Participants to whom the devices were dispensed, and a complete written explanation for any discrepancies (e.g., lost or damaged devices).

2.6 CO-INVESTIGATORS. Institution and Principal Investigator shall appoint as many additional investigators (hereinafter "Co-Investigators") as deemed necessary for conducting the Clinical Trial. All Co-Investigators shall abide by all provisions of the Trial Protocol, Agreement, and applicable laws, as detailed in Section 2.1.

2.7 NO AGENCY. Neither Institution nor any agent, representative, associate or employee of Institution, including, without limitation, Principal Investigator and Co-Investigators shall be considered an agent, representative or employee of Sponsor for any purpose. Conduct and control of work to be performed under this Agreement by Principal Investigator and Co-Investigators, lies solely with Institution. Except as explicitly permitted

in this Agreement, Institution, Principal Investigator and Co-Investigators may not incur any liability on Sponsor's behalf nor bind Sponsor to any contractual or payment obligation without the prior written consent of Sponsor.

3. SPONSOR OBLIGATIONS.

3.1 PROVISION OF INVESTIGATIONAL DEVICES, TRAINING, AND SERVICE. Sponsor shall provide Institution and Principal Investigator with pre-clinical and clinical information regarding the System. Sponsor will train in person or via training videos the Principal Investigator, and all support personnel, on the proper operation of the product. Sponsor will provide Protocol, CRFs, and instructions necessary for Clinical Registry Study participation.

3.2 MAINTAINANCE OF ADAQUATE SUPPORT PERSONNEL. Sponsor shall maintain throughout the Clinical Trial adequate support personnel to complete essential functions such as basic monitoring and data analysis. Sponsor maintains the right to use outside consultants or agents to complete all support functions.

4. COMPENSATION.

4.1 COMPENSATION. In consideration for performance of the Trial, Sponsor shall pay therein and/or reimburse Institution according to the Compensation Plan attached hereto as **Exhibit B** ("Compensation Plan"). All payments set forth on Exhibit "B" are inclusive of all associated costs, fees and charges, including any relevant or applicable overheads due to any party, entity or institution. Each Investigator acknowledges and agrees that his or her judgment with respect to his or her advice to and care of each subject is not affected by the compensation Institution receives hereunder.

4.2 BASIS OF COMPENSATION. The parties acknowledge and agree that the compensation set forth herein represents the fair market value of the services to be provided by Institution and Investigators to Sponsor, negotiated in an arm's-length transaction, and has not been determined in a manner which takes into account the volume or value of referrals or business, if any, that may otherwise be generated between Sponsor, on the one hand, and Institution and Investigators, on the other. Nothing contained in this Agreement, including any payment hereunder, is intended to be, nor shall it be construed as (a) an obligation or inducement, either express or implied, for Institution or Investigators to purchase, prescribe, promote or otherwise support specific Sponsor products; (b) a reward for any such purchase, prescription, promotion or other support by Institution or Investigators; or (c) a requirement that Research Institution or Investigators refer any patients or other business to Sponsor, or enroll any subjects in the Trial. The parties acknowledge and confirm that no such expectations exist.

4.3 NO ADDITIONAL COMPENSATION. The compensation set forth in Section 4.1 above is intended to compensate Institution, Principal Investigator and any additional Co-Investigator(s) for their participation in the Clinical Registry Study / Clinical Trial, and for performing the work necessary to comply with the terms of this Agreement. The compensation set forth here is the only compensation available to Institution, Principal Investigator and any additional Co-Investigator(s) for participating in the Clinical Registry Study / Clinical Trial. Furthermore, no compensation is payable to Patient Participants who enroll in the Clinical Registry Study / Clinical Trial.

4.4 SUBMISSION LIMITS. Institution and Investigators shall not and shall ensure that no Trial Personnel (a) submits claims for payment by any patient, third-party payor or any other person or entity for any item, procedure or service that has been paid for or provided without charge by Sponsor; or (b) seeks or retains payment from Sponsor for any item, procedure or service that is reimbursed by any patient, third-party payor or any other person or entity.

4.5 FINANCIAL REPORTING AND DISCLOSURE BY SPONSOR. Sponsor will have the right at its discretion (a) to disclose, as may be required under federal or state law, or as is otherwise desired by Sponsor (i) information relating to the services performed pursuant to this Agreement, including without limitation any and all payments, reimbursement for expenses, or other transfer of value made in other than dollar form relating to this Agreement; (ii) identifying information concerning Institution and Investigators; and (iii) any other information relating to this Agreement or to the Trial; and (b) to disclose such information to employers and affiliated institutions of Institution and Investigators, to any other individuals or entities involved in the Trial, and to regulatory agencies.

4.6 FINANCIAL REPORTING AND DISCLOSURE BY INSTITUTION AND INVESTIGATORS.

(a) Records. Institution and Investigators agree to keep records regarding all payments made, and costs, expenditures and expenses incurred in connection with the services performed pursuant to this Agreement, and shall provide Sponsor with information and supporting evidence regarding these payments, costs, expenditures and expenses that Sponsor determines it may be required to disclose under federal or state law, or otherwise desires to disclose. Such information shall be provided to Sponsor no less than thirty (30) days after receipt of such request.

5. TERM. The term of this Agreement shall commence on the Effective Date and shall end six months after completion of the study and data collection. See section 14 for survivability clause.

6. TERMINATION.

13. 6.1 GENERAL. Either party may terminate this agreement immediately upon email notice with no pre-warning with or without cause. Institution will be entitled to payment for un-cancelable obligations incurred through the termination date. This agreement will be governed by the laws of the State of Utah. Any arbitration or court cases emanating from this work will be in Salt Lake City, Utah.

6.2 COMPENSATION UPON TERMINATION. After termination, total compensation due to Institution shall be determined by the number of completed CRFs submitted and approved by the Monitor. Sponsor will provide compensation in accordance with Section 4.1 above for Patient Participants studied prior to the termination date for which CRFs have not yet been received by Sponsor, provided that a completed CRF is received by Sponsor within two weeks of the termination date. To the extent the Trial Protocol requires continued patient follow-up, Sponsor will provide compensation in accordance with Section 4.1 above for Patient Participants treated prior to the termination

date (i.e., Institution and Principal Investigator are required to continue and complete follow-up evaluations for all Patient Participants enrolled prior to receipt of termination even if the follow-up visits occur after termination).

14. 7. CONFIDENTIALITY OF SPONSOR INFORMATION. All information ("Confidential Information") obtained from Sponsor relating to the development, production, marketing or use of the System and all information obtained in the performance of the Clinical Trial which a reasonable person would consider to be confidential, is considered to be confidential information of Sponsor. Institution agrees to maintain all information in confidence and not release it to anyone without written consent from Sponsor or prior public disclosure by Sponsor. This provision will not apply to Confidential Information: (a) after it becomes publicly available through no fault of the Institution or Institution's employees or agents, (b) which is later released by Sponsor in writing; (c) which is lawfully obtained from third parties without restriction; (d) which can be shown to be previously known or developed by Institution or Institution's employees or agents independently of Sponsor or the Clinical Trial, or (e) which is required by law to be disclosed. To protect Sponsor's confidentiality, Institution agrees not to release the System, its components documentation or labeling to anyone other than those individuals participating in the Clinical Trial without Sponsor's prior written consent. Any agreements pertaining to confidentiality of the System, made between the Sponsor and the Institution prior to this Agreement, are herein expressly contained in this Agreement. Sponsor shall be provided with patient identifying information as allowed by law and agrees to maintain the confidentiality of all such patient information in compliance with applicable federal and state laws. Clinic will comply with all HIPAA regulations related to patient information confidentiality and privacy - <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>

8. PUBLICATION. The Institution and Principle Investigator agree to provide Sponsor with the opportunity to review and comment on all abstracts, manuscripts, and presentations at least 30 days prior to submission.

15. 9. INTELLECTUAL PROPERTY. All ideas, inventions, improvements, suggestions and rights to any invention made in the direct performance of the work conducted under the terms and conditions of this Agreement and in accordance with the Protocol shall belong solely to Sponsor. Institution and any persons who perform work under this Agreement, including, but not limited to, Principal Investigator and Co-Investigator(s), agree to convey to Sponsor, at the request of Sponsor and in a form satisfactory to Sponsor, the sole and exclusive ownership thereto, upon the payment of costs by Sponsor, if any, incurred by Institution in the filing, prosecution or maintenance of any patent application or patent issuing therefore. Such application, if any, will be filed and prosecuted by Sponsor. Any other inventions, unrelated to the Protocol or the work conducted under the terms and conditions of this Agreement, shall be owned by the Institution. For such inventions Sponsor shall have an option to acquire worldwide exclusive license. Sponsor must notify the Institution of its intention to exercise such option in writing. The right to option must be exercised within 120 days after notification of such discovery. Any IP you develop independently on your own belongs to you. Any IP we develop belongs to us. Any IP developed during this

study as a direct link result byproduct of the protocol and products we have provided for the study belongs to us.

10. DATA. Institution acknowledges that all information set forth in the CRFs as required under the Clinical Registry Study Trial Protocol, or data otherwise acquired during the Clinical Trial shall be the sole property of Sponsor. However, Institution retains the right to use such data for its own purposes and programs, in accordance with the terms of this Agreement, excluding, however, the use of such data in other clinical trials. Upon expiration or earlier termination of this Agreement, Institution shall use such data only upon Sponsor's prior written approval. Institution shall be obligated to store such data, and make such data available to Sponsor for five (5) years after completion or termination of the Clinical Trial.

11. INDEMNIFICATION

11.1 The Institution and PI have been are informed that this an early stage product development that is not yet proven to be safe or effective despite any animal or laboratory studies that have been conducted. There are a long list of potential risks associated with the procedure and the device that is detailed in the study protocol and informed consent form for the study. The Institution and PI indemnify the manufacturer and their suppliers and all their officers, employees and consultants of any liability associated with the use of the device in this safety evaluation study. Patient consent forms and process should also be clear to indemnify all the involved manufacturers and personnel from all liabilities except blatant purposeful uncontestable fraud.

11.2 SUBJECT INJURY. Sponsor shall not reimburse Institution for the expenses of care or treatment of any illness or injury to a patient which resulted directly from participation in the clinical trial.

12. NOTICES.

12.1 Any and all notices, requests, demands and other communications which are required or may be given under this Agreement shall be in writing, preferably by email, and shall be deemed to have been duly given when received if personally delivered; when transmitted if transmitted by telecopy or email; the day after it is sent, if sent for next-day delivery to a domestic address by a recognized overnight delivery service (e.g., Federal Express), as follows:

If to Sponsor: **Howard Leonhardt**
Leonhardt's Launchpads Utah, Inc.
370S, 300 E
Salt Lake City, Utah 84111
Email: howard@leonhardtventures.com
Phone: (954) 401-0096

If to Institution:

XXXXXXXXXX

XXXXXXXXXXXXXX

XXXXXXXXXXXXXX

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13. MISCELLANEOUS.

13.1 SURVIVABILITY. All covenants of the parties which are expressly intended hereunder to be performed in whole or in part after expiration or earlier termination of this Agreement, including, without limitation, the covenants stated in Sections 2.2, 2.4, and in Sections 5 through 11, and any representations, warranties or indemnities made in this Agreement by either party to the other, shall survive the expiration or earlier termination and be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

16. 13.2 BREACH. Each provision of this Agreement to be performed by a party shall be deemed both a covenant and a condition and shall be a material consideration for the performance of each other party's obligations hereunder. Any breach thereof by a party shall be deemed a material default hereunder. Company reserves right to demand halt of enrollment in clinical registry study at any time even without breach of any contractual terms or protocol deviations. This agreement will be governed by the laws of the State of Utah. Any arbitration or court cases emanating from this work will be in Salt Lake City, Utah.

13.3 CONSENT. The consent or approval by one party to any act by the other for which such consent or approval was required shall not be deemed to imply consent or approval, or waiver of the necessity of obtaining such consent or approval for the same or any similar acts in the future. No waiver, consent or approval shall be implied from silence or any failure of a party to act, except as otherwise specified in this Agreement.

13.4 REMEDIES. All rights, remedies, undertakings, obligations, options, covenants, conditions and agreements contained in this Agreement or provided by law shall be cumulative and no one of them shall be exclusive of any other. A party may pursue any one or more of its rights, options or remedies hereunder or may seek damages

or specified performance in the event of the other party's breach hereunder, or may pursue any other remedy by law or equity, whether or not stated in this Agreement.

13.6 ENTIRE AGREEMENT. This Agreement, the documents referred to herein and the exhibits hereto and thereto, constitute the entire agreement between the parties hereto pertaining to the subject matter hereof, and the final, complete and exclusive expression of the terms and conditions thereof. All prior agreements, representations, negotiations and understandings of the parties hereto, oral or written, express or implied, are hereby superseded and merged herein unless otherwise noted. Any agreements, understandings, warranties or representations not expressly contained in this Agreement shall in no way bind any party.

13.7 FURTHER ASSURANCES. Each party to this Agreement shall execute all instruments and documents and take all actions as may be reasonably required to effectuate this Agreement.

13.8 SEVERABILITY. If any provision of this Agreement as applied to either party or to any circumstance shall be adjudged by a court of competent jurisdiction to be void or unenforceable for any reason, the same shall in no way affect (to the maximum extent permissible by law) any other provision of this Agreement, the application of any such provision under circumstances different from those adjudicated by the court, or the validity or enforceability of the Agreement as a whole.

13.9 AMENDMENTS. No addition to or modification of any provision contained in this Agreement shall be effective unless fully set forth in a writing signed by all parties.

13.10 COUNTERPARTS. This Agreement may be executed in more than one counterpart, each of which shall be deemed an original, but all of which together shall constitute but one and the same instrument. The facsimile/electronic signature of a party shall be considered an original.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed this Clinical Trial Agreement as of the date first written above.

**INSTITUTION/
PRINCIPAL INVESTIGATOR:**

By: _____

Name:

Title:

SPONSOR:

Leonhardt's Launchpads Utah, Inc.

By: _____

Name: Howard J. Leonhardt

Title: Executive Chairman & CEO