

## Clinical Study Agreement

(for Institution/Investigator Initiated Study)

This Clinical Study Agreement (hereinafter, this "**Agreement**") is made this is entered into as of the last date of execution on the signature page, (the "**Effective Date**"), by and between \_\_\_\_\_, having an address at \_\_\_\_\_ (the "**Company**"), The Medical Research, Infrastructure and Health Services Fund of the Tel Aviv Medical Center, 6 Weizmann St., Tel Aviv 64239, Israel (the "**Institution**"), Prof./Dr. \_\_\_\_\_ acting hereunder as an employee of the Hospital (as defined below) and as the principal investigator of the Study (the "**Principal Investigator**"). Each of the Company, the Institution and the Principal Investigator may be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

**WHEREAS**, Institution is a health corporation - "Ta'agid Briut"- operating under Israeli legislation, that has the authority under applicable law and by separate agreement to enter into this Agreement and utilize the premises and personnel of The Tel-Aviv Sourasky Medical Center ("**Hospital**") to which it is affiliated, for the purpose of conducting clinical trials;

**WHEREAS**, the Institution desires to carry out a study evaluating the Company's \_\_\_\_\_ product (the "**Product**") as detailed in the Protocol attached hereto as Appendix A hereto (the "**Protocol**"), which was initiated by the Principal Investigator in cooperation with the Company (the "**Study**");

**WHEREAS**, the Company is interested in supporting the Study through providing the Product, financing for the Study and access to other non-tangible resources of the Company for support of the Study;

**WHEREAS**, the Institution acknowledges and affirms that it is familiar with and understands the applicable professional and legal requirements governing clinical studies and that it is capable of complying with such requirements;

**WHEREAS**, the Institution and the Company have agreed to enter into this Agreement setting forth the terms pursuant to which the Study shall be performed by the Institution.

**NOW, THEREFORE,** in consideration of the Parties' mutual covenants and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. The preamble to this Agreement and the representations contained therein constitute an integral part of the Agreement.
2. The appendices attached to this Agreement, as specified hereunder, constitute an integral part of the Agreement.
3. The Institution shall carry out the Study to be led by the Principal Investigator using the facilities and personnel of Hospital. In the event that the employer-employee relationship between the Principal Investigator and Hospital and/or the Institution is terminated for any reason, and/or in the event the Principal Investigator goes on leave and/or is unable and/or unwilling to carry out his duties under this Agreement, for any reason, the Institution may appoint a substitute Principal Investigator in place of the Principal Investigator subject to the prior written approval of the Company. If the Institution does not find a replacement principal investigator acceptable by the Institution and the Company within 30 days of termination of the engagement with the original Principal Investigator, then the Company shall have the right to terminate this Agreement with immediate effect.
4. Institution and Principal Investigator shall:
  - 4.1. be solely responsible for the Study and shall assume all obligations as sponsor of the Study - the Company shall not be deemed as sponsor of the Study;
  - 4.2. obtain all required legal authorizations required under Israeli law (whether preliminary or during the Study), including the approval of Hospital's ethics committee or and conduct the Study strictly in accordance with the terms of any such approvals;
  - 4.3. maintain insurance coverage as it is required under Israeli law; the Company shall be responsible to maintain its own insurance to cover its liabilities with respect to the Product and this Agreement;
  - 4.4. promptly report Serious Adverse Events (SAE) from the Study and send them to Company in writing immediately when they learn of such SAE; and
  - 4.5. provide Company with a copy of the final Clinical Study Report within an estimated period of \_\_\_\_ months after the final data lock of the Study, including all data collected by the Institution, in form

and detail agreed upon by the Parties.

5. The performance period of the Study and completion of a final written report will be from \_\_\_\_\_ through to \_\_\_\_\_.
6. Notwithstanding the aforesaid in Section 5 above, the Institution may terminate this Agreement and/or the Study upon the occurrence of one (or more) of the following events:
  - 6.1. by a written notice to the Company thirty (30) days in advance for any \_\_\_\_\_ reason.
  - 6.2. if the Ministry of Health and/or Helsinki Committee have voided, directly or indirectly, its approval of the Study or has conditioned its approval on conditions, as to which the Institution has notified the Company that it does not intend and/or is unable to comply with these conditions in whole or in part – immediately.
  - 6.3. The Company breaches this Agreement by a material breach and does not cure such material breach within thirty (30) days after having received a notice in writing from the Institution demanding a cure \_\_\_\_\_ of \_\_\_\_\_ the \_\_\_\_\_ material \_\_\_\_\_ breach.
  - 6.4. Due to patient's health safety concerns based on the product provided by the Company, as reasonably determined by the Institution- immediately
7. In the event of termination of the Study, the Company shall not be required to make any further payments for the Study, that were due after the date of such termination, and the Institution shall have no claim, demand or argument against the Company with respect to such non-payment. In addition, not later than seven (7) days after termination of the Study, the Institution shall provide the Company with all of the Data (as defined hereunder) collected prior to such termination, in the form set forth in the protocol, and the Company shall be free to analyze and use such Data.
8. The Company shall provide the Institution the Product and the financial support, as specified in **Appendix A** attached hereto.
9. Each Party may disclose to the other Party certain of its scientific, technical or business data or information (the “**Confidential Information**”). The receiving Party shall have the limited right to use the Confidential Information solely as necessary in performance of its commitments under this Agreement. During the term of this Agreement and for a period of seven (7) years after its expiration or earlier termination, the receiving Party shall maintain the Confidential Information in strict confidence, shall not transfer or disclose Confidential Information to any third party, and shall not use the Confidential Information for any purpose other than as expressly set forth

above, without the disclosing Party's prior written authorization; provided that such restrictions shall not apply to the extent that the information:

- (i) is in or enters the public domain through no fault of receiving Party;
- (ii) is lawfully made available to receiving party by an independent third party owing no obligation of confidentiality to the disclosing Party;
- (iii) is already in the receiving party's possession at the time of receipt from the disclosing Party and such prior possession can be properly documented and evidenced by the receiving Party;
- (iv) is independently developed by employees of receiving Party without reliance upon Confidential Information, and such independent development can be properly documented and evidenced by receiving Party;
- (v) is required by a legitimate order of an authorized governmental authority or agency to be disclosed by receiving party; provided, however, that receiving Party gives the disclosing Party prior written notice of such disclosure, to the extent reasonably possible, to permit the disclosing Party to seek a protective order or other similar order to prevent or limit such disclosure, and thereafter only discloses the minimum Confidential Information necessary in order to comply.

10. The Company shall own all right, title and interest in and to any and all intellectual property rights and other proprietary information provided in writing by the Company to the Institution and/or to the Principal Investigator and his/her team.

All data generated under the Study, including those defined in the Protocol (“**Data**”), shall be the property of the Institution. The Company shall be entitled to use the Data for research and internal purposes.

All results generated under the Study, including those defined in the Protocol (“**Results**”), shall be the property of the Institution. If the Company shall wish to obtain exclusivity to commercialize the Results, this shall be subject to the conclusion of a separate written license agreement.

11. No Warranty. THE DATA IS BEING SUPPLIED WITH NO WARRANTIES, EXPRESS OR IMPLIED, AND FUND AND PRINCIPAL INVESTIGATOR EXPRESSLY DISCLAIM ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.
12. Publications. The Institution shall have the first right to publish the Data and/or the Results. The Institution agrees to submit a copy of all manuscripts

and/or abstracts which report results of the Study, to the Company for review and comment thirty (30) days prior to its publication. The Company will have said thirty days to review publication. Company will have no editorial rights over manuscripts, but may comment on and request redaction of confidential or proprietary information of the Company, or any other information that might jeopardize intellectual property rights of the Company and/or of its products. In the event that the Company would like to submit an application for registration of any intellectual property for protection of its interests in such intellectual property – then the Institution shall be detained from making any such publication, for sixty (60) days, so to enable the Company to properly submit such application.

13. Use of Names. Unless otherwise required by applicable law, the Company's name will be used in any such publication only if and when permitted by the Company (such permission to include the form and context of such publication with the Company's name). The Company shall not use the name of the Institution and/or Hospital and/or their employees without the Institution's \_\_\_\_\_ prior \_\_\_\_\_ written \_\_\_\_\_ approval.
14. Independent Contractors. This Agreement shall not create relations of agency and/or partnership and/or employer-employee relations between the Company and the Institution and/or Hospital and/or the Principal Investigator.
15. Governing Law; Jurisdiction. This Agreement shall be exclusively governed by the laws of the State of Israel. Any dispute, controversy or claim arising under, out of or relating to this Agreement (and subsequent amendments thereof), its validity, binding effect, interpretation, performance, breach or termination, including tort claims, shall be exclusively referred to the competent courts in Jerusalem, Israel.
16. No Waivers. A Party to this Agreement shall not be considered as waiving its rights which it has acquired pursuant to the same and by virtue thereof because it has failed to ensure the immediate enforcement of any right or because it has granted another party an extension or delay, and a waiver or extension granted in one case shall not be considered or regarded as a waiver or extension in another, whether in the same matter or in another matter.
17. Force Majeure. Notwithstanding the aforesaid in this Agreement, a delay in the performance of an obligation imposed on any Party due to an event which falls under the definition of the term "Force Majeure" shall not be considered a breach of the Agreement, and performance of the said obligation shall be deferred until a date when the hindrance is removed, whereas the schedule will be amended accordingly, unless the performance has become, due to the delay, unreasonable under the circumstance of the matter. For purposes of this Agreement, the term "Force Majeure" shall mean acts of war, acts of terror, sabotage, general conscription, decisions of

legal tribunals (including injunctions, whether temporary or permanent), the acts and omissions of an authority operating pursuant to law, statute, strikes, state of emergency at Hospital, and general stoppage of the economy, natural disasters and other events that are not under the reasonable control of the party alleging the occurrence of the event if that same party alleging the occurrence of the said event has taken all reasonable measures to prevent their occurrence and/or continuance.

18. Amendments. Any change or addition to this Agreement shall be made in writing and with the signatures of the Parties hereto only.
19. Entire Agreement. This Agreement shall replace any prior representation, engagement, arrangement or agreement between the Parties the subject matter of which is the Study, and voids them to the extent that they exist.
20. Notice and Addresses
  - 20.1. The addresses of the Parties for purposes of this Agreement shall be as specified above.
  - 20.2. A Party who shall change its address will submit notice of the same within a reasonable time to the other Party.
  - 20.3. A notice that must be submitted pursuant to this Agreement will be delivered to the Parties at the addresses specified above, by personal delivery.
  - 20.4. Any notice submitted in accordance with this section shall be considered as if delivered to its address after the passing of one business day from the date on which receipt has been confirmed.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement:

SPONSOR *[replace with name of entity]*

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

PRINCIPAL INVESTIGATOR

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Date: \_\_\_\_\_

THE MEDICAL RESEARCH, INFRASTRUCTURE AND HEALTH SERVICES  
FUND OF THE TEL AVIV MEDICAL CENTER

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

