

## Clinical Trial Agreement

### (Medical Device)

This Clinical Trial Agreement (this "**Agreement**") is entered into as of the last date of execution on the signature page, between the undersigned parties, by and between \_\_\_\_\_, a company organized and existing under the laws of \_\_\_\_\_ (the "**Company**"), and the The Medical Research, Infrastructure and Health Services Fund of the Tel Aviv Medical Center, 6 Weizmann St., Tel Aviv 64239, Israel ("**Institution**"), and Prof./Dr. \_\_\_\_\_, having Israeli I.D. No.: \_\_\_\_\_ (the "**Principal Investigator**"). Each of Sponsor, Institution, and the Principal Investigator may be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

Whereas: -

- a. Sponsor has expressed its interest in managing the Clinical Trial, the subject of which is \_\_\_\_\_ (hereinafter: the "**Trial**"), with Company's code name \_\_\_\_\_, bearing protocol No. \_\_\_\_\_ a copy of which is attached as **Appendix A** hereto (the "**Protocol**"); and
- b. Sponsor has warranted that it is the sole owner of the intellectual property rights in the Product, as defined below, and the Protocol, and that there is no impediment under any law and/or agreement to the performance and execution of this Agreement by Sponsor; and
- c. 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; and
- d. Institution and the Principal Investigator have the ability, the facilities and the staff to perform the Trial, and Institution and the Principal Investigator have agreed to perform the Trial, exercising commercially reasonable efforts, in line with GCP, without any promise of success; and
- d. Sponsor has agreed to pay Institution the consideration, specified in **Appendix C** hereto, for the performance of the undertakings of the Principal Investigator and Institution under this Agreement in a full and timely manner; and
- e. Sponsor shall not pay the Principal Investigator any consideration, it being agreed that the Principal Investigator will conduct the Trial under the auspices of Institution and in consideration of whatever compensation Institution will pay to the Principal Investigator pursuant to a separate agreement among them.

**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. Preamble and Appendices**

- a. The preamble to this Agreement and the representations contained therein constitute an integral part of the Agreement.
- b. The appendices appended to this Agreement, as specified hereunder, constitute an integral part of the Agreement: -
  - Appendix A - Protocol
  - Appendix B - List of Trial Personnel
  - Appendix C - Trial Budget and Schedule of Payments
  - Appendix D - Warrants of Sponsor
- c. The provisions of this Agreement shall prevail - in the event of a contradiction or non-compliance - over the provisions of any appendix attached to this Agreement or which shall be attached hereto in the future, unless said appendix explicitly provides that its provisions shall prevail over this Agreement. However, existing and/or future Ministry of Health regulations and/or mandatory guidelines shall prevail over the provisions of this Agreement and/or any appendix provided that said regulations and/or mandatory guidelines are stricter regarding Sponsor's undertakings than Sponsor's undertakings under this Agreement and/or any appendix. Institution shall notify Sponsor in writing of any regulations or mandatory guidelines which supersede the provisions of this Agreement, as early as practicable once it becomes aware of such regulations or mandatory guidelines.

**2. Definitions**

In this Agreement, the following terms when capitalized shall have the following meanings set forth below:

"Ministry of Health Approval"	Approval of the Director General of the Israeli Ministry of Health, or to whomever he/she delegated the authority for this purpose, for the performance of the Trial by Institution according to the National Health Regulations.
"Hospital"	Tel Aviv Sourasky Medical Center.
this "Agreement"	This Agreement and its appendices.
the "Product(s)"	_____
the "Trial"	As defined in Preamble clause "a", i.e., the Clinical Trial, which shall be performed under this Agreement and the Protocol, as

each may be modified or updated from time to time subject to the consent of Institution and Company in writing and in advance.

the "Helsinki Declaration"	The Declaration containing the recommendations guiding investigators in bio-medical trials involving human beings, Helsinki 1964, as amended in Tokyo, 1975 and a draft of which appears in the attachment to the National Health Regulations.
"Protocol"	As defined in Preamble clause "a", and appended hereto as Appendix "A" to this Agreement.
"Trial Plan"	The plan that has been and/or will be approved by the Ministry of Health, containing a Schedule for conducting the Trial and the budget for the Trial derived from the activity necessary for performing the Trial (the " <b>Budget</b> "), and which is attached to this Agreement as Appendix "A."
the "IRB"	The Internal Review Board appointed pursuant to the National Health Regulations, the role of which is to approve any medical experiment on human subjects that will be conducted by Institution.
"Trial Personnel"	The team that shall be employed by the Hospital or Institution for conducting the Trial, including the Principal Investigator, as specified in Appendix "B".
"Participants in the Trial"	A group of persons chosen by the Principal Investigator according to criteria established in the Protocol.
"GCP"	Ethical and scientific quality standards for designing, conducting, recording, and reporting trials that involve the participation of human subjects, as customized by Institution.
"National Health Regulations"	National Health Regulations (Medical Trials on Humans), 5741-1980.

### 3. The Engagement

- 3.1 Upon signing this Agreement, Sponsor appoints Institution and the Principal Investigator, and those two parties undertake, each of them pursuant to its authority and respective obligations, to perform the Trial according to the stages thereof, within the framework and by means of the Hospital, while complying with the schedule, the Budget and the Protocol in Appendix "A," and while complying with the demands and terms established by the Ministry of Health, and all pursuant to the terms and conditions of this Agreement.
- 3.2 Notwithstanding sub-section 3.1 above, in the event that the employer-employee relationship between the Principal Investigator and the Hospital and/or 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, Institution may appoint a substitute Principal Investigator in place of the Principal Investigator subject to the prior written approval of Sponsor, which shall not unreasonably be withheld. In case that a substitute Principal Investigator is not appointed within 30 days from the date that the Principal Investigator ceases to fulfill its obligations pursuant to this Agreement, then, without derogation from the Parties respective rights, Sponsor may terminate this Agreement by a written notice with immediate effect.

- 3.3 It is hereby acknowledged that Sponsor may conduct, and/or engage with third parties in order to conduct additional clinical trials concerning the Products and/or any other products, as it shall see fit.

#### 4. **The Term of the Agreement**

- 4.1 Subject to the terms of this Agreement, the term of the Agreement (the "Term") shall be the duration of the Trial as defined in the Protocol, which shall commence on \_\_\_\_\_ and end upon completion of the Trial and fulfillment of all of the Parties' obligations under this Agreement.
- 4.2 Notwithstanding the aforesaid in sub-section 4.1 above, the Parties may bring this Agreement to an early end at any time, in writing, upon the occurrence of one (or more) of the following events: -
- 4.2.1 by a written notice to the other Parties thirty (30) days in advance.
- 4.2.2 if the Ministry of Health has voided, directly or indirectly, its approval of the Trial or has conditioned its approval on conditions, as to which Institution has notified Sponsor that it does not intend and/or is unable to comply with these conditions in whole or in part, and in such case the Agreement shall be terminated ten (10) days after such notice shall have been provided to Sponsor.
- 4.2.3 A Party breaches this Agreement and does not cure such breach within thirty (30) days after having received a notice in writing from the other Party demanding a cure of the breach in reasonable detail so that the breaching Party is on notice of the nature of the breach, provided, however, that Institution may not terminate this Agreement pursuant to a breach and/or breaches thereof, committed by the Principal Investigator.
- 4.2.4 A Party initiates bankruptcy or liquidation proceedings or a receiver is appointed over a substantial part or all of its assets, and such proceedings are not ceased within a period of ninety (90) days from the time that they have commenced.
- 4.2.5 An adverse effect occurs to the Participants in the Trial, which, in the absolute discretion of Institution and/or the Principal Investigator and/or the IRB, jeopardizes the safety of the Participants in the Trial and/or the Trial Personnel, and prior notice thereof is given immediately to Sponsor by any member of the Trial Personnel and the

Principal Investigator within a reasonable time from the discovery of such adverse effect. In such case the Agreement shall be terminated immediately after such notice shall be sent.

For the removal of any doubt, it is agreed that the Principal Investigator may not terminate this Agreement under this section.

- 4.3 For the avoidance of any doubt, the termination of this Agreement, for any reason, other than a material breach of this Agreement by Institution and/or the Principal Investigator, shall not prejudice Sponsor's undertaking to pay Institution for all services and expenditures of Institution and non-cancelable commitments incurred prior to such termination with regard to the performance of this Agreement.

## 5. The Trial

- 5.1 Sponsor shall supply to the Principal Investigator the Products and/or parts of the Product and/or the materials from which the Product is composed, without consideration, at the necessary pharmaceutical standard, all in accordance with the Protocol and in the quantities provided in the Protocol.
- 5.2 The Trial shall be performed by the Trial Personnel and managed by the Principal Investigator at the Hospital facilities, while making use of the Hospital's resources.
- 5.3 The Principal Investigator shall carry out the Trial in accordance with this Agreement, the Protocol, GCP, and all the relevant laws and regulations prevailing in Israel and in accordance with all necessary permits and/or licenses from the relevant authorities.
- 5.4 In performance of the Trial, Institution shall employ, directly or indirectly, the Trial Personnel, which will comprise the individuals specified in the list appended herewith and marked as Appendix B to this Agreement.
- 5.5 Subject to the provisions of sub-section 11 below, the representatives of Sponsor shall have the right to examine, study, make copies of and exploit in any other manner as they shall see fit the results, notes and other documents and representations obtained during the course of the Trial, during regular working hours, after providing advanced written notice and at a reasonable time.

To avoid any doubt, it is clarified that this sub-section and any provision of this Agreement shall not be deemed as providing management and/or supervision authority to Sponsor or to anyone on its behalf over the Trial and/or the Principal Investigator and/or whomever of the Trial Personnel.

- 5.6 In performance of the Trial, pursuant to this Agreement, Sponsor undertakes to continue to supply the Product to Institution and/or the Hospital, without consideration, in order to complete the commenced treatment of the Participants of the Trial at the Principal Investigator's sole and reasonable discretion, or as part of the Protocol, should one of the Participants of the Trial become dependent on the Product.

To avoid any doubt, it is hereby clarified that this obligation of Sponsor shall remain in effect even in the event that the Agreement has been terminated or is voided for any reason, but only for so long as it shall be required under the guidelines of the Ministry of Health.

- 5.7 Notwithstanding Sponsor's undertakings under this Agreement, Sponsor undertakes to abide by all the relevant laws and regulations prevailing in Israel and in accordance with all necessary permits and/or licenses from the relevant authorities.
- 5.8 Without derogating from the generality of the foregoing, the Parties shall perform the Trial in accordance with the terms specified in the Israeli MOH Guidelines titled "Clinical Trials of Human Subjects" issued in May 2020 (hereinafter referred to as "**Ministry Guidelines**") including without limitation Form 4 to the Ministry Guidelines titled "Sponsor's Commitment Form – Clinical Trials with an Investigational Product", that will be attached to this Agreement as **Appendix D** and serve as an integral part of this Agreement
- 5.9 Sponsor represents that it will monitor and evaluate all applicable safety procedures in the performance of the Trial, and ensure the good quality of the Trial performance and/or products and/or equipment (including the Product) used in the Trial. This requirement shall not derogate from the Parties' commitment to perform the Trial in accordance with all ethical requirements applicable to clinical trials.
- 5.10 Sponsor is responsible to ensure that the research methods and processes of the Trial are safe and ethical, and Sponsor shall use trained and qualified research teams in connection with the Trial. Furthermore, Sponsor shall ensure that the data provided is reliable and valid and that all the results and/or reports made by Sponsor shall be statistically accurate, ethical and unbiased. Sponsor shall keep Institution informed regarding material adverse effects relating to the Product that occur at other trial sites or that it otherwise becomes aware of.
- 5.11 Without derogating from the above, the Parties hereby undertake to keep in confidence, not to transfer to any person and/or entity and not to make any use of any individually identifiable health information in a way that would prejudice a patient's privacy whether or not he/she ultimately participates in the Trial. This obligation shall survive any termination or expiration of this Agreement indefinitely. For avoidance of doubt, patient medical records shall remain the exclusive property of Institution.
- 5.12 Upon termination of the Trial and promptly upon Institution's written request, Sponsor shall at its own cost and expense collect all unused Products from Institution at Institution's place of business.

## 6. **Supply of Materials.**

- 6.1. During the Trial and as an integral part of the Trial as detailed in the Protocol, Sponsor wishes to obtain certain biological materials (as detailed in the Protocol) from Participants of the Trial (the "**Materials**"). Sponsor warrants with respect to such Materials, as follows:

- 6.1.1 It has obtained all necessary approvals and permits required under law to perform the Trial (including with respect to the usage of the Materials) and there is no impediment under any law or agreement to execute the Trial;
- 6.1.2 The Materials shall be used solely for the purposes expressly detailed in the Protocol and Sponsor shall not use the Materials for any purpose other than expressly defined in the Protocol and shall not conduct any analysis or modification of the Materials. Particularly, the Materials shall not be utilized in, or co-mingled with, any other research projects and/or programs ongoing now or in the future by Sponsor.
- 6.1.3 Upon the earlier of the expiration or termination of this Agreement, Sponsor, at its own cost and expense shall return or destroy all unused Materials. Sponsor shall promptly provide Institution with a written confirmation that all Materials have been destroyed or returned to Institution, as the case may be.
- 6.1.4. It shall not transfer and/or sell and/or lease and/or directly or indirectly commercialize the Materials and/or any part thereof and/or let any third party, directly or indirectly, examine the Materials and/or the results of such examination, for whatever purpose. Sponsor shall allow access to the Materials only to such personnel to whom access is necessary for the conduct of the research described in the Protocol.
- 6.1.5 It shall at all times use the Materials in a safe manner and shall at all times comply with all applicable Israeli laws, rules and regulations (including all Israeli Ministry of Health regulations and/or guidelines) pertaining to the Materials and the use thereof.

## **7. Reporting and Follow-Up**

- 7.1 The Principal Investigator shall meet with the representatives of Sponsor, during the customary working hours and to a reasonable extent, in order to report to Sponsor, on an ongoing and consecutive basis, and in order to update Sponsor in all matters related to the performance of the Trial, its progress, difficulties, solutions, etc.
- 7.2 The Principal Investigator, upon the completion of the Trial, shall prepare the case reports forms (CRF) legibly and accurately (or ensure that a co-Investigator does so) and shall make the CRF available to Sponsor.
- 7.3 The Principal Investigator hereby undertakes to adhere to the accuracy of the Trial results as required by the Helsinki Declaration and the GCP.

## **8. Financing of the Trial**

- 8.1 In consideration for the performance of the Trial under this Agreement, Sponsor shall pay Institution the consideration specified in Appendix C to this Agreement on the dates specified in Appendix C. Such payments shall be made against a proper invoice render a

reasonable time in advance of the due date for the payment. No payments shall be made directly to the Principal Investigator.

- 8.2 To avoid any doubt, it is hereby clarified that Institution and/or the Principal Investigator shall not perform any acts which deviate from the acts specified in the Protocol and/or are specifically mentioned in this Agreement unless Institution has approved said acts, in advance and in writing.

## 9. **Indemnity and Insurance**

- 9.1 Sponsor shall indemnify and hold harmless the Hospital, Institution, the Principal Investigator, the Trial Personnel and all other employees of the Hospital and Institution (the "**Indemnitees**") from and against any loss, damage, liability and expense (including reasonable legal costs) arising out of or resulting from the use of the Products and/or materials which have been supplied by Sponsor and/or from conducting the Trial in accordance with the Protocol.

The indemnity may be proportionately reduced and shall not apply to the extent of claims or losses arising from a material breach by any of the Indemnitees of the Protocol, GCP, Helsinki Declaration, National Health Regulations, and/or any other Israeli applicable law or regulation relating to the Trial.

- 9.2 Sponsor will be notified promptly and in writing of any complaint or claim promptly after Institution becomes aware of the same. Sponsor will be given absolute and sole discretion in the defense and settlement of any such complaint or claim. Institution shall cooperate with and give Sponsor reasonable assistance in connection with any such claim or proceedings at Company's cost and expense.
- 9.3 Sponsor hereby undertakes that, unless the Indemnitees in question agree otherwise in writing, any and all settlements of claims by Sponsor and/or its insurers will be free of admission of any liability whatsoever on the part of the Indemnitees.
- 9.4 Without derogating from Sponsor's liability under this Agreement and/or under any applicable law, including the Ministry of Health Directive, Company undertakes to present Institution an Insurance Certificate according to the law of Israel and the Guidelines of the Ministry of Health. The Certificate will specifically include the following provisions:

Type of insurance – one of the following:

No Fault Insurance for Clinical Trial with a specific sub-limit of not less than \$3,000,000 for any one occurrence and in the aggregate.

or

Liability Insurance including coverage for Clinical Trials with a specific sub-limit of not less than \$3,000,000 for any one occurrence and in the aggregate.

The policy shall include as additional insureds: Institution, the Hospital, their employees, the Principal Investigator, sub-investigators, the Ethics Committee and any medical personnel involved in performing the Trial.

The insurance coverage shall be in force until the completion or termination of the Trial and for all relevant periods thereafter, and the discovery period shall be of seven (7) years (and in the case of minors, seven (7) years after they reach the age of eighteen (18)). The insurance must contain a specific provision whereby no cancellation or limitation of cover shall be effected, unless thirty (30) days advance written notice thereof be given to Institution by registered mail. Upon cancellation or non-renewal or absence of valid insurance in accordance with the foregoing, Institution shall be entitled to terminate this Agreement forthwith upon providing a written termination to the other Parties. The territory limits and jurisdiction shall include Israel.

- 9.5 Without derogating from Company's indemnification obligations, if during the course of the Trial a Participant in the Trial suffers an injury as a result of the Product or properly performed procedures required by the Protocol ("**Subject Injury**"), Company, subject to the following restrictions contained herein agrees to pay all medical expenses necessary to treat such Subject Injury. Injury shall not be considered Subject Injury, to the extent that injury is due to (i) the negligence, recklessness or willful misconduct of Institution, or (ii) the failure of Institution or Investigator to follow the Protocol, good clinical practices, any applicable laws or regulations.
- 9.6 Disclaimer of Warranty. Nothing contained in this Agreement shall be construed as a warranty by Institution or the Investigator that the results of the Trial will be useful or commercially exploitable or of any value whatsoever. In addition, and without derogating from the aforementioned Institution and the Investigator disclaim all warranties, either express or implied, with respect to the Trial results and any products that incorporate, integrate or are designed based in whole or part, on the Trial results, including without limitation implied warranties of merchantability, efficacy and fitness for a particular purpose.
- 9.7 Exclusion of Consequential Damages. Subject to the above regarding indemnification, neither Party shall be liable (whether under contract, tort (including negligence) or otherwise) to the other Party, or to any third party for any indirect, incidental or consequential damages, including, without limitation, any loss or damage to business earnings, lost profits or goodwill and lost or damaged data or documentation, suffered by any person, arising from and/or related with and/or connected to this Agreement even if such Party is advised of the possibility of such damages.
- 9.8 Sponsor's undertaking under this section shall survive the expiration or termination of this Agreement for whatever reason.

## 10. **Intellectual Property**

- 10.1 Each Party retains all right, title and interest in any patent, patent application, trade secret, know-how and other intellectual property that was owned by such Party prior to the Effective Date of this Agreement and/or that is created or arises outside the scope of this Agreement, and no license grant or assignment, express or implied, by estoppel or otherwise, is intended by, or shall be inferred from this Agreement.
- 10.2 Subject to Section 10.1, all rights and title to and/or interests in the results directly derived from the Trial and/or the Product as well as any inventions or discoveries invented or discovered directly in connection therewith (hereinafter, collectively the "**IP**") shall be exclusively owned by Company.

## 11. **Exploitation of the Trial Results**

It is hereby agreed that Sponsor has and shall have the sole and absolute right, without limitation of time or place, worldwide (i.e., in Israel or abroad), subject only to limitations under the law and the regulations of the Ministry of Health, to make any and all uses of the IP, including without limitation to manufacture and/or market and/or sell and/or grant a right of use in the production and/or marketing rights of the Product and/or accompanying products which shall derive from the Trial, directly or indirectly, and rights to perform research and development on said IP, including any modifications and/or improvements of the same.

## 12. **Confidentiality**

- 12.1 Institution and the Principal Investigator undertake to keep in confidence, not to transfer to any person and/or entity and not to make any use, other than for purposes of the performance of the Trial, any information, data or know-how, whether orally or in writing, which shall come into their possession in relation to and/or in connection with the Trial, the Trial Results and/or the Product and/or the IP (hereinafter - the "**Confidential Information**"). Institution and the Principal Investigator further undertake to ensure that the Trial Personnel shall also comply with the aforesaid confidentiality and non-use undertakings.

The obligations of non-disclosure and non-use shall not apply to the following:

(1) Information that is or becomes publicly available other than as a result of breach of this Agreement by the Investigator, the Trial Personnel or Institution;

(2) Information that is already independently known by the Investigator, or employees of Institution and/or the Hospital, prior to its disclosure by Sponsor hereunder or under any other agreement between the Investigator and/or Institution and Sponsor, as evidenced by contemporaneous written records; or

(3) Information that was independently developed by employees of Institution or of Hospital without relying upon the Confidential Information as evidenced by contemporaneous written records; or

(4) Information at or after such time that is disclosed, without any restrictions on the use and/or disclosure thereof, to the Investigator or Institution or the Hospital or their

employees, by a third party that Institution may reasonably assume has the right and authority to make such disclosure; or

(5) Information that the disclosure thereof is required under any law, court writ or any competent authority, provided that, to the extent that it is legally permitted to do so, the Party so required shall provide the other Party with a prompt notice of such requirement and shall reasonably cooperate with the other Party (at the other Party's expense) in challenging and/or limiting the scope of such disclosure.

12.2 The obligations of non-disclosure and non-use hereunder shall continue for 7 (seven) years after the termination of this Agreement for any reason whatsoever.

12.3 Neither Party shall disclose this Agreement and the terms hereof, or use the name of the other Party or any of their respective employees or service providers (including the Investigator) in any marketing, advertising, press release or other promotional literature or any other publicity, without the other Party's prior written consent, all except for any mention in any applications to official authorities for regulatory approval or in the fulfillment of any duty owed to any competent authority (including a duty to make regulatory filings and/or reports).

### 13. **Publications**

13.1 The Principal Investigator and Institution hereby undertake to submit to Sponsor all drafts of any publications proposed for publication by the Principal Investigator and/or any member of the Trial Personnel, no later than sixty (60) days prior to the submission of any form of such publication or drafts thereof to any journal, publisher, and/or any other third party.

13.2 Sponsor hereby undertakes to inform the Principal Investigator and Institution as early as practicable following the receipt of such draft of any changes and/or deletions the Principal Investigator is to perform in such publications, required for the purpose of preserving the confidentiality and proprietary rights of Sponsor under this Agreement. It is agreed that the Principal Investigator and/or Institution shall not make any publication of information to which Sponsor objects under this Section 13.2.

13.3 Without derogating from the above, Sponsor hereby undertakes to abide by the rules of publications issued by the Ministry of Health including and without limitation the Ministry Guidelines, or any guidelines issued in addition thereto or in substitution thereof.

13.4 As a condition for performing the Trial, Sponsor shall be responsible for publishing the Study on the MyTrial website, <https://my.health.gov.il/CliniTrials/Pages/Home.aspx>, in accordance with the Ministry Guidelines, if applicable.

### 14. **Relations of the Parties**

This Agreement shall not create relations of agency and/or partnership and/or employer-employee relations between Sponsor and Institution and/or Hospital and/or the Principal Investigator and/or the Trial Personnel.

**15. Suspending Conditions**

The Parties hereby agree and undertake that the Agreement shall not enter into effect before the three (3) following cumulative approvals shall have been granted with regard to the Trial:

15.1 Approval of the Protocol by the IRB and/or by the Ministry of Health, if required by the Regulations.

Promptly following the execution of this Agreement, the Principal Investigator shall submit the Protocol to the IRB to obtain approval for conducting the Trial and/or to the Ministry of Health, if required by the Regulations.

15.2 Approval of the Agreement in general and its Budget by the Ministry of Health and specifically by the Contracting Committee of the Ministry of Health.

15.3 Pursuant to Section 9.4 of this Agreement, a written Certificate of Insurance shall be provided to Institution.

**16. Governing Law and Jurisdiction**

16.1 This Agreement shall be exclusively governed by the laws of the State of Israel.

16.2 Any dispute, controversy or claim arising under, out of or relating to this Agreement shall be subject to the exclusive jurisdiction of the competent courts in Tel Aviv-Jaffa, Israel.

**17. Non-Waiver of Rights**

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.

**18. Endorsement, Assignment and Transfer**

A Party to this Agreement shall not transfer, endorse or assign its debts, obligations or rights pursuant to and by virtue of this Agreement, or a part thereof, all as the case may be to any third party, unless the prior written consent of all the other Parties has been obtained.

**19. Cooperation between the Parties**

The Parties shall take all actions necessary to execute the provisions of this Agreement, and shall, respectively ensure that all the decisions required by this Agreement will be made and all the acts performed. The Parties shall cooperate with each other and shall act in good faith in all things relating to their engagement in this Agreement and all matters derived therefrom.

**20. Force Majeure**

- 20.1 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.
- 20.2 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 the Hospital, and general stoppage of the economy, epidemic, 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.

## 21. **Interpretation**

- 21.1 Any change or addition to this Agreement shall be made in writing and with the signatures of the parties hereto only.
- 21.2 In the event it is determined that any provision of this Agreement - which does not constitute a material and basic term herein - is invalid, illegal or unenforceable, this will be insufficient to cause the avoidance of the rest of the provisions of this Agreement and/or to affect the validity, legality or the possibility of the enforcement of the rest of the provisions, as stated.
- 21.3 This Agreement shall replace any prior binder, representation, engagement, arrangement or agreement between the parties the subject matter of which is the Trial, and voids them to the extent that they exist.

## 22. **Notice and Addresses**

- 22.1 The addresses of the parties for purposes of this Agreement shall be: -  
 Sponsor –  
 Institution - as detailed in the preamble to the agreement  
 The Principal Investigator – at Institution.
- 22.2 A Party who shall change its address will submit notice of the same within a reasonable time to the other Party.
- 22.3 A notice that must be submitted pursuant to this Agreement will be delivered to the Parties at the addresses specified above, by personal delivery.

22.4 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 set their hands on the date and at the location set forth above: -**

\_\_\_\_\_  
Sponsor

\_\_\_\_\_  
Institution

\_\_\_\_\_  
The Principal Investigator

**Appendix A**

**Appendix C**

When payment is made by way of bank transfer, the Sponsor shall notify Institution's financial department so as to enable it to identify such transfer, to the following contact person:

Shalom Zaretsky, CPA R&D – [shalomz@tlvmc.gov.il](mailto:shalomz@tlvmc.gov.il)

Such notification shall include the following information: sum transferred, name of Sponsor/CRO transferring Institutions, name of Principal Investigator, and Protocol or Ethics Committee number.