

Clinical Trial Agreement

(with CRO)

This Clinical Trial Agreement (this "**Agreement**") is entered into as of the last date of execution on the signature page, by and between _____, with offices at _____ (the "**Company**"), The Medical Research, Infrastructure, and Health Services Fund of the Tel Aviv Medical Center, with offices at 6 Weizmann Street, Tel Aviv 64239, Israel (the "**Fund**"), and _____ an individual with offices at 6 Weizmann Street, Tel Aviv 64239, Israel (the "**Principal Investigator**"). The Company, the Fund and the Principal Investigator may be referred to herein individually as a "**Party**" and collectively as the "**Parties**".

Whereas: -

- a. The Company has expressed its interest in managing a clinical trial, the subject of which is _____ (the "**Trial**"), bearing Protocol No. _____, a copy of which is attached as **Appendix A** hereto (the "**Trial Protocol**");
- b. The Company has warranted that the Sponsor, as defined below, is the sole owner of the intellectual property rights in the Product, as defined below, and the Trial Protocol, and the Company has the permission from Sponsor to execute this Agreement and is acting as an agent of the Sponsor and there is no impediment under any law and/or agreement to perform and execute this Agreement;
- c. The Fund and the Principal Investigator have the ability, the facilities and the staff to perform the Trial, and the Fund and the Principal Investigator have agreed to perform the Trial, without any promise of success;
- d. The Company has agreed to pay the Fund the consideration, specified in **Appendix C** hereto, for the performance of the undertakings of the Principal Investigator and the Fund under this Agreement; and
- e. The Company shall not pay the Principal Investigator any consideration, it being agreed that the Principal Investigator will conduct the Trial under the auspices of the Fund and in consideration of whatever compensation the Fund will pay to the Principal Investigator pursuant to a separate agreement between them.

Therefore it has been declared, stipulated and agreed between the Parties as follows:

1. Preamble and Appendices

- a. The preamble to this Agreement and the representations contained therein constitute an integral part of this Agreement.

- b. The appendices appended to this Agreement, as specified hereunder, constitute an integral part of this Agreement: -

Appendix A - Trial Protocol

Appendix B - List of Trial Personnel

Appendix C - Trial Budget and Schedule of Payments

Appendix D - Warrants of Sponsor

Appendix E – Indemnification by 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 guidelines shall prevail over the provisions of this Agreement and/or any appendix provided that said regulations and/or guidelines are stricter regarding the Company's undertakings than the Company's undertakings under this Agreement and/or any appendix.

2. Definitions

In this Agreement, the following terms shall have the following meanings:

"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 the Fund according to the National Health Regulations.

"Hospital" The Tel-Aviv Sourasky Medical Center.

"Sponsor" _____.

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 Trial Protocol, as each may be modified or updated from time to time subject to the consent of the Fund and the Company in writing and in advance, and subject to receipt of all applicable Helsinki Committee/IRB approvals.
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.
"Trial Protocol"	as defined in Preamble clause "a", and appended hereto as <u>Appendix A</u> 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, and which is attached to this Agreement as <u>Appendix A</u> .
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 the Fund.
"Trial Personnel"	the team that shall be employed by the Hospital or the Fund for conducting the Trial, including the Principal Investigator.
"Participants in the Trial"	A group of persons chosen by the Principal Investigator according to criteria established in the Trial Protocol.
"GCP"	Ethical and scientific quality standards for designing, conducting, recording, and reporting trials which involve the participation of human subjects, as customized by the Fund.
"National Health Regulations"	National Health Regulations (Medical Trials on Humans), 5741-1980.

3. The Engagement

- 3.1 Upon signing this Agreement, the Company appoints the Fund and the Principal Investigator, and they undertake to perform the Trial within the framework and by means of the Hospital,

while complying with the schedule, the Trial Budget and the Trial 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 the Fund 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 Fund may appoint a substitute Principal Investigator in place of the Principal Investigator subject to the prior written approval of the Company, which shall not unreasonably be withheld.

4. Company Warranties and Undertakings

Without derogating from the Company's obligations under applicable laws and regulations, the Company warrants and undertakes:

- 4.1 There is no impediment under any law and/or agreement to execute this Agreement.
- 4.2 It acts as an agent of Sponsor and is authorized to make all warranties and undertakings on behalf of Sponsor and any warranty and/or undertaking made on behalf of Sponsor is binding on Sponsor.
- 4.3 On behalf of itself and on behalf of Sponsor, that both Company and Sponsor shall abide by the rules of publications issued by the Ministry of Health including and without limitation the Guidelines for the Conduct of Clinical Trials in Human Subjects issued by the Israeli Ministry of Health in 2006, and any guidelines issued in addition thereto or in substitution thereof.
- 4.4 On behalf of itself and on behalf of Sponsor, that both Company and Sponsor shall perform the Trial in accordance with the terms specified in the Israeli MOH Guidelines titled "Clinical Trials of Human Subjects" issued on February 2016 (hereinafter referred to as "Ministry Guidelines") including without limitation Appendix 4 and Appendix 5 to the Ministry Guidelines titled "Warrants of the Sponsor", that will be attached to this Agreement as **Appendix D** and serve as an integral part of this Agreement.
- 4.5 On behalf of itself and on behalf of Sponsor, that both Company and Sponsor 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, each according to its role under this Agreement. This requirement shall not derogate from the Parties' commitment to perform the Trial in accordance with all ethical requirements applicable to clinical trials.
- 4.6 The Company is responsible, on behalf of the Sponsor, to ensure that the research methods and processes of the Trial are safe and ethical, and that the Sponsor shall use trained and qualified research teams in connection with the Trial. Furthermore, the Company, on behalf of the Sponsor, shall ensure that the data provided is reliable and valid and that all the results and/or reports made by the Sponsor shall be statistically accurate, ethical and unbiased. The

Company is responsible, on behalf of the Sponsor, to keep the Fund informed regarding material adverse effects relating to the Product that occur at other trial sites.

- 4.7 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 the Fund.

5. The Term of the Agreement

- 5.1 Subject to the provisions of this Agreement, the term of the Agreement shall be the duration of the Trial as defined in the Trial Protocol, which shall commence on _____ and end upon completion of the Trial (the "**Term**").
- 5.2 Notwithstanding the aforesaid in sub-section 5.1 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: -
- 5.2.1 by a written notice to the other Parties thirty (30) days in advance.
 - 5.2.2 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 the Fund has notified the Company 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 sent to the Company.
 - 5.2.3 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.
 - 5.2.4 A Party enters into bankruptcy or liquidation proceedings or a receiver is appointed over part or all of its assets, and such proceedings are not ceased within a period of forty five (45) days from the time that they have commenced.
 - 5.2.5 An adverse effect occurs to the Participants in the Trial, which, in the absolute discretion of the Fund 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 to the Company 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, this 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.

- 5.3 For the avoidance of any doubt, the termination of this Agreement, for any reason, shall not prejudice the Company's undertaking to pay the Fund for all services and expenditures owing, and non-cancellable expenses incurred under this Agreement prior to the termination of the Agreement.

6. The Trial

- 6.1 The Company 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 schedule and in the quantities provided in the Trial Protocol.
- 6.2 The Trial shall be performed and managed by the Principal Investigator at the Hospital facilities, while making use of the Hospital's resources.
- 6.3 The Principal Investigator shall carry out the Trial in accordance with the Trial 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.
- 6.4 In performance of the Trial, the Fund 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.
- 6.5 To avoid any doubt, it is hereby clarified that the Fund and/or the Principal Investigator shall not perform any acts which deviate from the acts specified in the Trial Protocol and/or are specifically mentioned in this Agreement unless the Fund has approved said acts, in advance and in writing.
- 6.6 Subject to the provisions of Section 13 below, the representatives of the Company shall have the right to examine 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 the Company or to anyone on its behalf over the Trial and/or the Principal Investigator and/or whomever of the Trial Personnel.

- 6.7 In performance of the Trial, pursuant to this Agreement, the Company undertakes to continue to supply the Product to the Fund 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 Trial Protocol, should one of the Participants of the Trial become dependent on the Product.

For avoidance of doubt, it is hereby clarified that this obligation of the Company 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.

- 6.8 Notwithstanding the Company's undertakings under this Agreement, the Company undertakes to abide by all the relevant laws and regulations prevailing in Israel and in accordance with and after all necessary permits and/or licenses from the relevant authorities.
- 6.9 Upon termination of the Trial, the Company shall at its own cost and expense collect all unused Products from Fund at Fund's place of business. In the event the Company shall not collect the Products and/or upon Company's request, the Fund shall destroy the Products and Company shall pay all cost and expenses related to the destruction of Products upon Fund's demand.

7. Supply of Materials.

- 7.1. During the Trial and as an integral part of the Trial as detailed in the Trial Protocol, the Company may obtain certain biological materials (as detailed in the Trial Protocol) from Participants of the Trial (the “**Materials**”). The Company warrants with respect to such Materials, as follows:
- 7.1.1 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;
- 7.1.2 The Materials shall be used solely for the purposes expressly detailed in the Trial Protocol and the Company shall not use the Materials for any purpose other than expressly defined in the Trial 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 the Company.
- 7.1.3 Upon the earlier of the expiration or termination of this Agreement, the Company, at its own cost and expense shall return or destroy all unused Materials. The Company shall promptly provide the Fund with a written confirmation that all Materials have been destroyed or returned to the Fund, as the case may be.
- 7.1.4. 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. The Company shall allow access to the Materials only to such personnel to whom access is necessary for the conduct of the research described in the Trial Protocol.
- 7.1.5 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.

8. Reporting and Follow-Up

- 8.1 The Principal Investigator shall meet with the representatives of the Company, during the customary working hours and to a reasonable extent, in order to report to the Company, on an ongoing and consecutive basis, and in order to update the Company in all matters related to the performance of the Trial, its progress, difficulties, solutions, etc.

- 8.2 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 the Company.
- 8.3 The Principal Investigator hereby undertakes to adhere to the accuracy of the Trial results as required by the Helsinki Declaration and the GCP.

9. Financing of the Trial

- 9.1 In consideration for the performance of the Trial under this Agreement, the Company shall pay the Fund 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 rendered a reasonable time in advance of the due date for the payment.
- 9.2 The Company shall pay the Fund the consideration under this Agreement irrespective whether or not the Sponsor has paid the Company the consideration in whole and/or in part.

10. Indemnity; Insurance

The Company shall procure that the Sponsor shall sign Appendix E to this Agreement.

11. Intellectual Property

- 11.1 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.
- 11.2 Subject to Section 11.1, 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 the Sponsor.

12. Exploitation of the Trial Results

It is hereby agreed that the 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.

13. Confidentiality

- 13.1 The Fund 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 (the "**Confidential Information**"). The Fund 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 the Fund;
- (2) Information that is already independently known by the Principal Investigator, or employees of the Fund and/or the Hospital, prior to its disclosure by Sponsor hereunder or under any other agreement between the Principal Investigator and/or the Fund and the Company, as evidenced by contemporaneous written records; or
- (3) Information that was independently developed by employees of the Fund or of the Hospital who have not been exposed to 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 Principal Investigator or the Fund or the Hospital or their employees, by a third party that the Fund 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.

- 13.2 The obligations of non-disclosure and non-use hereunder shall continue for seven (7) years after the expiration or termination of this Agreement for any reason whatsoever.
- 13.3 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 Principal Investigator) in any marketing, advertising, press release or other promotional literature or any other publicity, without the other Party's prior written consent (which consent shall not be unreasonably withheld or delayed), 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).

14. Publications

- 14.1 The Principal Investigator and the Fund hereby undertake to submit to the Company 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.
- 14.2 The Company hereby undertakes to inform the Principal Investigator and the Fund 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 the Company under this Agreement. It is agreed that the Principal Investigator and/or the Fund shall not make any publication of information to which the Company objects under this Section 14.2.
- 14.3 Without derogating from the above, the Company hereby undertakes to abide by the rules of publications issued by the Ministry of Health including and without limitation the Guidelines for the Conduct of Clinical Trials in Human Subjects issued by the Israeli Ministry of Health in 2006, or any guidelines issued in addition thereto or in substitution thereof.
- 14.4 As a condition for performing the Trial, the company shall be responsible for publishing the Trial in the NIH web sites in accordance with the instructions of the General Manager of the Israeli Ministry of Health published in 18/2/08.

15. Relations of the Parties

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

16. 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:

- 16.1 Approval of the Trial Protocol by the IRB and/or by the Ministry of Health, if required by the Regulations. The Principal Investigator shall submit the Trial Protocol to the IRB to obtain approval for conducting the Trial and/or to the Ministry of Health, if required by the Regulations.
- 16.2 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.
- 16.3 Sponsor shall sign **Appendix D** and **Appendix E** to this Agreement and shall provide Fund with a written Confirmation of Insurance.

17. Governing Law and Jurisdiction

- 17.1 This Agreement shall be exclusively governed by the laws of the State of Israel.
- 17.2 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 Tel Aviv, Israel.

18. Non-Waiver of Rights

A Party to this Agreement shall not be considered as waiving 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.

19. 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 the other party has been obtained.

20. Cooperation between the Parties

The Parties shall take all actions necessary to execute the provisions of this Agreement, and shall cause that at each one of them 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.

21. Force Majeure

- 21.1 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 this 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.
- 21.2 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, 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.

22. Interpretation

- 22.1 Any change or addition to this Agreement shall be made in writing and with the signatures of the Parties hereto only.
- 22.2 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.
- 22.3 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.

23. Notice and Addresses

- 23.1 The addresses of the Parties for purposes of this Agreement shall be: -

The Company – [...]

The Fund - 6 Weizmann Street, Tel-Aviv

The Principal Investigator – at the Fund.

- 23.2 A Party who shall change its address will submit notice of the same within a reasonable time to the other party.
- 23.3 A notice that must be submitted pursuant to this Agreement will be delivered to the parties at the addresses specified above, by personal delivery.
- 23.4 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.

[Signature Page Follows]

**In witness whereof the Parties set their hands
on the date set forth above: -**

The Company

The Fund

Principal Investigator

Appendix C

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

Shalom Zaretsky, CPA R&D – shalomz@tlvmc.gov.il
Vera Balanter, R&D Bookkeeper – verab@tlvmc.gov.il

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

Appendix E

To: Medical Research, Infrastructure, and Health Services Fund
of the Tel Aviv Medical Center
6 Weizmann Street
Tel Aviv, 64239
Israel.

Re: The Agreement signed on the _____ between _____ (the "Company"), the Medical Research, Infrastructure, and Health Services Fund of the Tel Aviv Medical Center (the "Fund"), and _____ (the "Principal Investigator") regarding the Clinical Trial bearing Protocol No. _____ (the "Agreement").

We the undersigned _____ sponsor of the above the Clinical Trial the subject of which being _____ (the "Trial") bearing protocol No. _____ (the "Trial Protocol") hereby warrant and undertake:

1. We are the sole owner of the intellectual property rights in the Product, as defined in the Agreement, and the Trial Protocol, and there is no impediment under any law and/or agreement to perform and execute the Agreement.
2. We have authorized the Company, pursuant to a written contract between ourselves and the Company, to execute the Agreement and agree to all terms of the Agreement and undertake jointly and severally with the Company and commit to abide by all undertakings under the Agreement. We shall be responsible for monitoring the Agreement.
3. Without derogating from the above, we hereby warrant and undertake:
 - 3.1 To indemnify and hold harmless the Tel Aviv Sourasky Medical Center, the Fund, the Principal Investigator, the Trial Personnel, the EC/IRB and all other employees of the Hospital and the Fund (the "Indemnitees") from and against any loss, damage, liability and expense (including legal costs) arising out of or resulting from the use of the Products and/or from conducting the Trial.

This indemnity is subject to the following conditions:

- 3.1.1 The indemnity shall not apply to the extent of claims or losses arising from a material breach by the Indemnitees of the Trial Protocol, GCP, Helsinki Declaration, National Health Regulations, and/or any other Israeli applicable law or regulation relating to the Trial.
- 3.1.2 We will be notified promptly and in writing of any complaint or claim promptly hereunder after the Fund becomes aware of the same.
- 3.1.3 We will be given absolute and sole discretion in the defense and settlement of any such complaint or claim.

- 3.1.4 The Fund shall cooperate with and give us reasonable assistance in connection with any such claim or proceedings at our cost and expense, and shall consent to any reasonable settlement of such complaint or claim approved by us.
4. We hereby undertake that any and all settlements of claims by us and/or our insurers will be free of admission of any liability whatsoever on the part of the Indemnities.
5. Without derogating from the Company's liability under this agreement and/or under any applicable law, including the Ministry of Health Directive, Company undertakes to present the Fund 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: the Fund, 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 7 years (and in the case of minors, 7 years after they reach the age of 18). The insurance must contain a specific provision whereby no cancellation or limitation of cover shall be effected, unless 30 days advance written notice thereof be given to the Fund by registered mail. Upon cancellation or non-renewal or absence of valid insurance in accordance with the foregoing, the Fund 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.

6. Our undertakings under this letter shall survive termination or expiration of the Agreement, for whatever reason.
7. This letter shall be exclusively governed by the laws of the State of Israel. Any dispute, controversy or claim arising under, out of or relating to the Agreement or this letter shall be exclusively referred to the competent courts in Tel Aviv, Israel.
8. All definitions in this letter shall have the same meaning as those in the Agreement, unless expressly stated otherwise.
9. Our address is _____.

Signature: _____.

Date: _____.