

נספח 5 :נספח גנטי

**Genetic Addendum
to Clinical Trial Agreement dated**

This Addendum (this "**Addendum**") is made this ___ day of _____ 2019, by and between _____, a company organized and existing under the laws of the State of Israel with offices at _____ (the "**Company**"), and The Medical Research, Infrastructure, and Health Services Fund of the Tel Aviv Medical Center, a health corporation organized and existing under the laws of the State of Israel with offices at 6 Weizmann Street, Tel Aviv 64239, Israel (the "**Fund**"), and _____ an individual residing at _____, and having Israeli I.D. No.: _____ (the "**Principal Investigator**"). Each of the Company, the Fund, and the Principal Investigator may be referred to herein as a "**Party**" and collectively as the "**Parties**".

Whereas:

(a) On _____, the Parties signed an agreement (the "**Main Agreement**") for the purpose of conducting a clinical trial (the "**Trial**"), bearing Protocol No. _____ (the "**Protocol**").

Or

(a) The Company is the sponsor of a clinical trial (the "**Trial**") bearing Protocol No. _____ (the "**Protocol**") and has authorized _____ ("**CRO**") to enter into an agreement for the purposes of conducting a clinical trial with the Fund (the "**Main Agreement**").

(b) During the Trial, and as an integral part of the Trial as detailed in the Protocol, the Company wishes to obtain certain biological specimens from the participants in the Trial (the "**Materials**") as described in the Protocol.

(c) The Company has warranted that 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.

- (d) This is an addendum to the Main Agreement which shall, after the signature hereof, form an integral part of, and be construed together with, the Main Agreement and its other appendices.

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

1. The preamble to this Addendum and the representations contained therein constitute an integral part of this Addendum.
2. The Company agrees that the Materials shall be used solely for the purposes expressly detailed in the Protocol, and it shall not use the Materials for any purpose other than expressly defined in the Protocol, and that it will 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.
3. Upon the earlier of expiration or termination of the Main Agreement and/or this Addendum, 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.
4. The Company agrees not to 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 the Company's 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 Protocol.
5. The Company 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.
6. Without derogating from the Company's undertaking not to use and/or examine the Materials other than within the scope of the Trial and for this purpose only, it is hereby expressed that the Company shall not have any right

or interest in the Materials and/or any part thereof and/or in any of the information which may be derived from the Materials other than the information resulting directly from the conduct of, or within the scope of, the Trial.

7. Subject to and without derogating from the Company's undertaking under the Main Agreement and/or the Company's undertakings not to use and/or examine the Materials other than for performing the Trial and for this purpose only, the Company hereby undertakes to keep in absolute confidence, not to transfer to any person and/or entity and not to make any use of any information derived from the Materials.
8. Without derogating from the Company's undertakings under any law and/or the provisions of the Main Agreement, the Company shall keep and shall procure that its employees and/or any third party on its behalf keeps in absolute confidentiality the names and identity of the participants in the Trial, the community they come from and/or live in and/or their ethnic background and/or national origin, should any such information come into their possession for whatever reason.
9. All obligations of the Company regarding indemnification and insurance under the Main Agreement and/or its appendices shall apply, mutatis mutandis, to any act and/or omission of the Company under this Addendum.
10. The obligations of the Company under this Addendum which, by their nature are ongoing obligations, shall survive the expiration or termination of the Main Agreement for whatever reason.
11. This Addendum 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 Addendum (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.

IN WITNESS WHEREOF, the Parties have executed this Addendum as of the Effective Date appearing above.

Company

**The Medical Research, Infrastructure
and Health Services Fund of the Tel
Aviv Medical Center**

By: _____
Title: _____

By: _____
Title: _____

By: _____
Title: _____

[PRINCIPAL INVESTIGATOR]