Procedure for Clinical Trials in Human Subjects 2020
Form 4
Sponsor commitment form - clinical trial with an **investigational product**

Date:

Institutional Application No.: 0000-00-RMC

We the undersigned hereby undertake

1) **Details of the Sponsor:**

Name of the sponsor:	
Name of the sponsor's representative in Israel:	
Protocol name/mark as provided by the sponsor:	
Protocol Title:	
Name of investigational product: (specify all investigational products)	
Name of the Principal Investigator:	Department:
The medical institution: Schneider Children's Medical Center	

1) The trial sponsor undertakes to act in accordance with the local and international procedures for clinical trials, and in particular on the following topics:

   - Quality management and monitoring of the course of the trial
   - Responsibility for the activities of vendors to whom trial authority has been delegated
   - Responsibility for the safety and integrity of the investigational product
   - Providing information about the trial to authorized parties
   - Reporting safety events
   - Handling information and saving documents

2) The trial sponsor undertakes that if it decides to publish the results of the clinical trial in scientific literature, it will publish it in full and without leaving things out of context.

3) The trial sponsor commits to maintain confidentiality and privacy protection, and not to use the genetic information and/or tissues for any other and different purpose than for what the approval was granted for.

4) The sponsor knows that the tissues and blood are not its private property and therefore, it is not entitled to transfer them to any third party, except to a third party that was lawfully approved in advance, and that produced an appropriate commitment in accordance with the requirements of the Supreme Committee for Clinical Trials in Human Subjects (commitment letter from the laboratory abroad).

5) **Insurance**: The insurance coverage for the trial exists as long as there is a valid approval by the director of the medical institution for the trial.

5.1) For a trial in which the sponsor is **a commercial company**: The sponsor commits to insure its legal liability under the laws of the State of Israel against claims, if submitted by clinical trial participants and/or third party claims. All in connection with the clinical trial, whether during the period of conducting the clinical trial or thereafter and in accordance with the guidelines of Procedure 14.

5.2) For a trial in which the sponsor is **a sponsor-investigator/academic institution/non-profit organization**: The signature of the medical institution director (or anyone authorized by him) on this document confirms the existence of appropriate insurance of the medical institution for the conductors of the trial.

- The sponsor will be informed of any claim or potential claim immediately after it is brought to the attention of the medical institution or the investigator.
- The investigator, the medical institution and its employees will provide the sponsor, upon its written request, reasonable support in any case of a claim filed against it, as stated above.

6) The sponsor commits to provide the medical institution with the investigational product/s, for the entire duration of the clinical trial and until its conclusion, free of charge. In addition, the sponsor commits to bear all the additional costs resulting from conducting the trial, provided that these costs are not a result of the standard medical treatment of the disease.

7) The sponsor commits to continue supplying the investigational product, free of charge, even after the end of the clinical trial, for a period of **three years**, subject to the following **conditions**:

- The physician in charge of the trial recommends that the best interest of the trial participant requires continued treatment with the investigational product.
- There is no other suitable alternative medical treatment according to the decision of the institutional committee.

8) For the purpose of continued administration for 3 years, the investigator and the institution undertake the following **conditions**:

- ✓ The physician in charge of the trial will write an orderly "follow-up treatment" protocol that will be approved by the Institutional Helsinki Committee and the director of the medical institution {in accordance with Regulation 29 (a) 5}. A copy of the protocol will be provided to the sponsor.
- ✓ The physician in charge will continue to monitor the patient's health condition and will report to the sponsor and the Helsinki Committee all the adverse events that occurred during the follow-up treatment, as is customary in clinical trials. The investigator will report to the sponsor and the Helsinki Committee at least once a year on the progress of the treatment and a final report will be submitted at the end of the period of the continued treatment.
- ✓ The medical institution in which "follow-up treatment" will be provided will make sure to provide appropriate insurance coverage for the responsibility of the medical institution and the investigators towards the patient, for the continued provision of the investigational product after the end of the clinical trial.

~~9)~~ The sponsor will be exempt from providing the product after the end of the trial in one of the following cases:

- Development of the product was stopped or the clinical trials with the product did not yield the hoped-for outcomes.
- The investigational product is intended for single administration or for a fixed period (not for treatment of a chronic condition).
- Giving the investigational product for an extended period is not suitable for the patient and may harm his health.
- When the investigational product was approved for marketing in the State of Israel and entered the basket for trial indication[1].
- When the investigational product is not a medical preparation, such as food / dietary supplement / medicinal plant / cannabis.

~~10)~~ This form constitutes an integral part of the agreement between the company sponsoring the clinical trial and the medical institution.

Sponsor: _____ _____ _____
Name Signature and Stamp Date

Medical Institution Director: _____ _____ _____
Name Signature and Stamp Date

Name of Principal Investigator:_____ _____ _____
Name Signature and Stamp Date

[1] In cases where the product will be registered in Israel and has entered the basket, and in the study, foreign nationals, people without civil status, refugees, etc. (who are not eligible to receive the product subsidized) are participating, attention is necessary for all the factors that also require that these participants continue to receive the product for a period of 3 years.