Procedures of Incentive Track No. 35 – A Plan to encourage the Establishment or Expansion of the Activities of Research and Development Companies of Foreign Industrial Corporations in the Fields of Biotechnology or Medicine (Pilot)

1. General

1.1. In accordance with the provisions of Section 15.2 of Incentive Track No. 35 - a plan to encourage the establishment or expansion of the activities of research and development companies of foreign industrial corporations in the fields of biotechnology or medicine (pilot) ("Incentive Track No. 35"), these procedures are an integral part of the incentive track. In case of conflict between the provisions of Incentive Track number 35 and these procedures, the provisions of Incentive Track No. 35 shall prevail.

1.2. The terms contained in this document are as defined in the Incentive Track 35 unless explicitly stated otherwise.

2. R&D Center Selection Process

2.1. The purpose of Incentive Track No. 35 is to enable large foreign industrial corporations engaged in the fields of biotechnology and medicine, as defined below, to establish or expand in the State of Israel the activities of companies they own directly or indirectly in the fields of R & D, technological innovation or production, while establishing or transferring part of their global economic activity in Israel.

2.1.1 Biotechnology:

(a) Ethical drugs based on a new and defined active substance (this definition includes RNA / DNA molecules, proteins, antibodies, and small molecules).
(b) Cell-based products for clinical uses, including gene therapy.
(c) New and original products based on the identification and application of new biochemical/cell methods.
(d) Products based on genetic engineering and production in transgenic animals or transgenic plants.

2.1.2 Medicine – one or more of the following:

(a) Medical diagnostic tools
(b) Medical devices and equipment
(c) The areas of digital health, including but not limited to: Mobile Health (MHealth), Health Information Technology (IT), Wearable Devices, Telehealth and Telemedicine, and Personalized Medicine, Genomics and Omics Technologies.

2.2. A bidder wishing to submit a proposal in the framework of a competitive process published by virtue of Incentive Track No. 35 shall fill out an proposal form for serving as an R & D center (**Appendix 1** to the Procedure) and attach to his proposal the documents detailed in section 4.4 of Incentive Track No. 35:

2.2.1. The bidder's certificate of incorporation.

2.2.2. An affidavit relating to the direct or indirect control of the bidder (**Appendix No. 2** to the procedure).

2.2.3. An affidavit regarding the employment of more than 50% of the R & D employees of the foreign corporation outside of Israel (**Appendix NO. 3** to the procedure).

2.2.4. An affidavit regarding the sales turnover of the foreign corporation, including of all of the corporations it holds, directly or indirectly (**Appendix No. 4** to the procedure).

2.2.5. An affidavit of the authorized signatory the bidder and of each of its shareholders, that none of them has a limited account and is not under the proceedings of receivership, stay of proceedings, dissolution, etc. (**Appendix No. 5** to the procedure).

2.2.6. An affidavit according to which the bidder and its controlling shareholders comply with the requirements of the Encouragement of Research and Development Regulations in Industry (Stipulation of Approvals - Minimum Wage), -2011 (**Appendix No. 6** to the Procedure).

2.2.7. An affidavit regarding the intention to employ at least 30 additional R & D employees at the end of three years from the inception date of the R & D center's eligibility period and continue employing the same number of employees for a period of at least two years from the end of the R & D center's eligibility period if it is an existing R&D center or employ at least 30 new R & D employees at the end of 3 years from the inception date of the R & D center's eligibility period and continue employing the same number of employees for at least two years from the end of the R & D center's eligibility period, if it is a new R&D center, as the case may be (**Appendix No. 7** to the procedure).

2.3. It should be clarified that the affidavits listed in section 2.2 above may be submitted in Hebrew and English. The affidavits in English should be attached with Hebrew translation as required and certified by a notary.

2.4. The manner of submission of bids shall be detailed in the framework of the public appeal for the preparation of the competitive process, which shall be published on the website of the Innovation Authority.

2.5. The R & D center shall be selected in a competitive process in accordance with the provisions of Incentive Track number 35 for a five-year eligibility period.

2.6. The decision of the committee shall be brought to the attention of the R & D center, which has been selected in writing, and shall include special conditions and milestones, if any, and written notice shall be sent to the other bidders who have not won in the competitive process.

2.7. The selected R & D center shall sign a letter of undertaking to the Innovation Authority as stated in section 4.13 of the Incentive Track 35, in accordance with the wording it receives and shall forward same to the department of contracts in the Innovation Authority("the Contracts Department"), together with the forms required for the approval and operation of the R & D center as specified below:

2.7.1. The form of opening/updating beneficiary details together with the documents specified in the form.

2.7.2. Extended CPA's approval for bookkeeping as required by law.

2.7.3. Confirmation of the tax assessment officer for income tax withholding exemption.

2.8. Two years after the end of the eligibility period, the R & D center shall submit an affidavit of its authorized signatories that it employed at least 30 additional R & D employees from the end of 3 years from the inception date of the R & D center's eligibility period and continued to employ them for at least two years from the end of the eligibility period of the R & D center, if it is of an existing R & D center, or employed at least 30 new R & D employees from the end of 3 years from the inception date of the R & D center's eligibility period and continued to employ them for a period of at least two years from the end of the R & D center, if it is of a new R & D center, as the case may be (**Appendix No. 8** to the procedure).

3. Receipt of approval for the files to be submitted by the R&D center selected in the process

3.1. Pursuant to section 5.1 of Incentive Track number 35, the R&D centers selected in the competitive process may submit for the approval of the committee files in the area of biotechnology or medicine during the eligibility period.

3.2. The submission of files and the related expenses and reports shall be according to what is specified in the procedures of the Innovation Authority below subject to the changes specified in section 3.3 below:

(A) **200-01** - Procedure on activity rules from the submission of the application for support until the end of the R & D period;
(B) **200-02** - Procedure on the application for support of R & D plan;
(C) **200-03** - Procedure on the management of the financial system for R & D purposes and submission of performance reports during and after the R & D period;
(D) **200-06** - Procedure on special approvals and applications.

3.3. Specific instructions for Incentive Track number 35:

3.3.1 Submission of files –

(a) The files shall be submitted for a performance period of not more than 36 months (this section supersedes section 3.3.2 of procedure **200-02** - procedure on the application for support of R & D plan.

(b) Files to be submitted in the fifth year of the R&D center's eligibility period shall be submitted for a period of up to 24 months such that they shall not exceed the total assistance period, as defined in section 2.25 of the Incentive Track number 35.

(c) The dates for submitting files on behalf of the R & D centers selected in the competitive process shall be published from time to time on the website of the Innovation Authority.

3.3.2 Annual Audit

During the years of the file, an annual audit shall be conducted (every 12 months). The audit shall be conducted in accordance with Section 3.10 of Procedure **200-03 -** Procedure on the Management of the Financial System for R & D Needs and Submission of Performance Reports during and after the Research and Development Period, which requires the submission of a final technical report, final financial report, CPA approval and statement of the R&D center.

4. Appendices to the procedure

Appendix 1 - Proposal form
Appendix 2 - Affidavit regarding direct or indirect control of the bidder
Appendix 3 - Affidavit regarding the number of employees of the foreign corporation outside of Israel
Appendix 4 - Affidavit regarding the sales turnover of the foreign corporation
Appendix 5 – Affidavit of the authorized signatory of the bidder
Appendix 6 – Affidavit regarding the compliance with requirements of the Encouragement of Research and Development Regulations in Industry (Stipulation of Approvals - Minimum Wage), -2011
Appendix 7 - Affidavit regarding the number of R & D employees to be employed by the bidder
Appendix 8 - Affidavit regarding the number of R & D employees employed by the bidder