Quality Assurance Agreement

This Quality Assurance Agreement (hereinafter, this "Agreement") is is entered into as of the last date of execution on the signature page, (the "Effective Date"), by and between _____ having its principal place of business at _____ (hereinafter - the "Sponsor"), and The Medical Research, Infrastructure, and Health Services Fund of the Tel Aviv Medical Center, a non-profit organization organized and existing under the laws of the State of Israel with offices at 6 Weizmann St. Tel-Aviv, Israel 64239 (hereinafter - the "Fund"). Each of the Sponsor and the Fund may be referred to herein individually as a "Party" and collectively as the "Parties".

Whereas:

(a) The Parties wish to cooperate in the conduct of clinical trials at the Tel Aviv Sourasky Medical Center (the "Hospital") (collectively, the "Clinical Trials"), and in connection therewith, the Parties wish to enter into this framework Agreement with respect to quality assurance matters;

(b) As part of the Clinical Trials, the Sponsor shall supply the Fund with the Study Drug (as such term is defined in each clinical trial agreement signed between the Fund and the Sponsor and/or by the Fund and the Sponsor's CRO relating to the relevant Clinical Trial) (each, a "CTA"), that will be held and handled by the pharmacy located at the Hospital (hereinafter referred to as “Pharmacy”); and

(C) Following publication and entrance into force of Israeli Ministry of Health ("MOH") Guidelines: GMP (Good Manufacturing Practices) for IMPs (Investigational Medicinal Products) No. EX-012/01, pursuant to the Pharmacists Regulations [GMP - Good Manufacturing Practices], the Parties wish this Agreement to apply to any future CTA.

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

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

2. The Fund represents and warrants that the Pharmacy is not a legal entity and is an integral part of the Hospital, and the Fund is entitled, by operation of the Israeli law and according to an agreement between the Fund and the Hospital to conduct clinical trials in the facilities of the Hospital and to use and exploit for such purpose, the Hospital's resources, facilities, personnel, etc. including the use of the Pharmacy.

3. **The Sponsor's responsibilities:**

3.1 The Sponsor shall have overall responsibility for the quality of the Study Drug as required by the regulatory requirements or any applicable law and will ensure that only

batches of the Study Drug meeting the regulatory requirements and relevant MOH Guidelines are provided to the Fund/Hospital. Furthermore, the Sponsor shall be responsible to ensure that the Pharmacy is supplied with the quantities of the Study Drug required for the conduct of a Study in accordance with the applicable CTA.

3.2 Before any CTA is executed, the Sponsor shall provide the Pharmacy with applicable Study Drug information to allow the Pharmacy to operate within the quality and storage requirements and in accordance with all applicable laws, regulations and guidelines.

3.3 To supply the Study Drug only after fulfillment of all requirements concerning proper manufacture and delivery as detailed in MOH Directive EX- 012/01. The Study Drug shall be supplied with a Packing list/Pro forma Invoice and a statement essentially stating that "The Study Drug has been released according to the MOH Directive EX-012/01".

3.4 In case of release and delivery made by a local distributor depot, the Sponsor shall be entitled to use only the services of a local distributor depot authorized by the MOH.

3.5 To retain all documentation related to the manufacture, control, storage, release, transport and delivery to the Pharmacy for the period required by the applicable law and guidelines, and all such documentation shall be made available at any time upon request of the Pharmacy.

3.6 To ensure that the Study Drug transport to the Pharmacy shall be carried out in full conformity with the applicable regulations and GMP to ensure that during the transport the Study Drug shall be stored, handled and transported in a proper and safe manner pursuant to the transportation conditions determined by the manufacturer of the Study Drug and in full compliance with the highest level of quality and safety for potential interim storage of IMPs and delivery up to the hand-over point at the Fund/Hospital.

3.7 To assure that no deviations occur during transportation (from temperature or from other relevant conditions needed for proper transportation). In case of any deviation occurring during transportation that affects the Study Drug quality, the Sponsor will immediately inform the Fund and/or the Pharmacist and will be responsible for assessing the deviation and acting accordingly to rectify the situation.

3.8 In case the Study Drug was delivered with the proper documentation as abovementioned - the receiver at the Pharmacy shall sign on the Packing list/Proforma Invoice of the package as prepared by the Sponsor or a distributor for delivery. The document should precisely specify the identity of the addressees. This confirmation of the Study Drug arrival to its destination should be documented and filed by the Pharmacy of the Fund and should be presented to the MOH upon request. If an electronic system is used (IXRS), the relevant party at the Fund will be trained in advance and will be responsible to confirm these shipments via the electronic system

3.9 To supply Study Drug manufactured, certified and re-certified under all applicable GMP regulations and standards, according to the meaning assigned to such terms in MOH GMP.

3.10 To attach to each supply of the Study Drug a certificate signed by the Authorized Person (as defined at the MOH GMP) stating fulfillment of all obligations and duties of the Sponsor concerning proper manufacture and delivery as detailed in the MOH GMP. However, this requirement shall not apply in case the Sponsor uses the services of a local distributor depot authorized by the MOH for the release and delivery of the Study Drug.

3.11 To use the services of a subcontractor that is licensed and authorized by law to distribute medicinal products to the Fund, under MOH GMP and all applicable regulatory requirements. To have a written and valid quality agreement with such subcontractor; to supervise and perform audits on such subcontractor to ensure compliance with all applicable regulatory requirements.

3.12 To provide the Pharmacy with written storage conditions, and or with the instructions for the administration/issuance of the Study Drug, where such instructions implement the requirements of the Study Drug label or the relevant protocol.

3.13 The Sponsor shall inform the Pharmacy before first shipment and coordinate with the Pharmacy its arrival and its quantity.

3.14 To support the Fund, including the Principal Investigator, study staff and the Responsible Pharmacist (as such term is defined in MOH Guidelines), with responses and information to any query or quality issue/concern related to the quality, efficacy or safety of the Study Drug, and to instruct the Fund with regard to the usage/ of the Study Drug or its collection by the Sponsor. If destruction of the Study Drug is required such shall performed by the Sponsor, at the Sponsor's sole discretion, instructions, cost and expense.

3.15 To provide the Fund a method for un-blinding a study medication, agreed upon with the Principal Investigator, in case of emergencies in accordance with and subject to any applicable laws, regulations and guidelines.

3.16 In case investigational product storage at the Study unit is necessary, rather than in the Pharmacy, the Sponsor or its designee will ensure that the Ethics Committee approval for storage at the Study unit is granted, and that the requirements for secured storage and proper storage conditions are met at the Study unit, and that procedures exist which define the mode of managing and reporting deviations from the proper storage conditions.

3.17 To notify the Fund of any regulatory action that may have an impact on the quality, efficacy and/or safety of the Study Drug (e.g. Warning Letter, product seizure, hold or recall, suspension or withdrawal of any relevant license, etc.). Notification shall be made no later than 48 hours after receipt of notice of the regulatory action.

3.18 To report to the Fund of any deviation from manufacturing, packaging, storing, transporting, distributing and testing requirements concerning each batch of the Study Drug.

3.19 To handle all deviations and investigations related to the manufacturing, packaging, storing, transporting, distributing and testing operations concerning the Study Drug that could affect its quality, safety and/or efficacy.

3.20 The Sponsor shall be responsible for labeling and relabeling. In case there is a need to perform relabeling at the Hospital/Study unit, it shall be performed by the Sponsor under the supervision of the Pharmacist.

4. The Fund's responsibilities:

4.1 To store the Study Drug only at the Pharmacy (unless otherwise permitted to be stored at the Study unit in accordance with the provisions of this Agreement).

4.2 To hold and maintain appropriate premises and equipment for the storage of the Study Drug, the study protocol and the Sponsor's written instructions (which are consistent with the Protocol). In particular, the Fund undertakes that the storage temperature at the Pharmacy will be controlled and monitored at all times by orderly calibrated measures and freezers as applicable, and that the premises and equipment shall be adequate to prevent cross-contamination, mix-up, and pest penetration.

4.3 To restrict access to the Pharmacy and particularly to the Study Drug, to the Pharmacy staff and the Principal Investigator only, and to take all appropriate technical and physical safeguards and measures to prevent theft, counterfeit, unauthorized access or misuse of the Study Drug. The Study Drug shall not be delivered/ transferred by the Pharmacy staff to any other person but the Principal Investigator, or to a person among the study staff delegated by the Principal Investigator to receive the Study Drug on behalf of the Principal Investigator.

4.4 Receipt of the Study Drug by the Fund shall be made by an authorized person delegated by the Responsible Pharmacist. Receipt shall be conducted in the Pharmacy.

4.5 To document on observed deviation and to promptly report to the Sponsor any such deviation or suspected deviation from storage conditions instructed by the Sponsor or the manufacturer of the Study Drug, and to fully comply with the Sponsor's instructions with regard to the usage of such Study Drug, its collection by the Sponsor and with regard to the CAPA (corrective and preventive actions) required by the Sponsor or mutually agreed by the Parties. To the extent required by law, the Fund will follow the notification duties that apply to it or to the Principal Investigator toward the MOH and the individuals using the Study Drug.

4.6 The Fund and the Principal Investigator will not transfer the Study Drug to any third party (except to the participants in the Clinical Trial), unless a prior written approval is received from the Sponsor. Unused/defective/expired Study Drug shall be collected by the Sponsor within 30 days of the Fund's request in writing. . Destruction activities shall not be performed at or by the Hospital and will be under the Sponsor's responsibility, in accordance with this Agreement and the applicable laws.

4.7 The Fund will maintain written SOPs (Standard Operating Procedures) for procedures comprising the handling of the Study Drug from the moment of its receipt and until its dispensation, including receipt procedures, storage, handling with deviations/defects and reporting duties, CAPA, stocktaking and returns . The Fund will conduct initial as well as periodical training for all of its employees and staff involved in such procedures.

4.8 In the event the Fund becomes aware of any suspicion of counterfeit, counterfeit incidents, theft or illegal handling with respect to Sponsor's Study Drugs, the Fund shall inform the Sponsor.

5. The term of this Agreement shall commence on the Effective Date and shall remain in effect for the duration of the Clinical Trial, unless earlier terminated in accordance with the provisions hereinbelow (the "Term"). Each Party may terminate this Agreement for any reason, including for reasons of convenience, by 30 days prior written notice. Notwithstanding the above, either Party may terminate this Agreement with immediate effect in the event that the other Party had breached this Agreement and did not cure such breach within a 14 (fourteen) day period after receipt of written notice from the terminating Party. Notwithstanding the above-mentioned, any CTA which was executed during the Term and any Clinical Trial subject of such CTA shall continue to be governed by any and all quality provisions contained herein (notwithstanding the termination of this Agreement as aforementioned).

6. Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that the Sponsor may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its affiliated companies; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement. Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

7. MISCELLANEOUS

7.1 The confidentiality provisions set forth in the relevant CTA shall govern the exchange of any quality related information shared between the Parties to such agreement including whereby any information is shared according to the provisions of this Agreement.

7.2 If any provision contained in this Agreement is determined to be invalid or unenforceable, in whole or in part, the remaining provisions and any partially enforceable provision will, nevertheless, be binding and enforceable, and the Parties hereby agree to substitute for the invalid provision a valid provision which most closely approximates the intent and the economic effect of the invalid provision.

7.3 The failure or delay of a Party to the Agreement to claim the performance of an obligation of the other Party shall not be deemed a waiver of the performance of such obligation.

7.4 Changes including supplements to this Agreement can only be made by mutual consent in writing between both Parties. All changes including supplements will be recorded in a change history relevant to the changed or supplemented document.

7.5 This Agreement shall be governed by the laws of the State of Israel. The courts located in Tel Aviv, Israel, shall have exclusive jurisdiction over any action arising under or relating to this Agreement.

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

Sponsor	**Date**	**Fund**	**Date**

Responsible Pharmacist's confirmation

I hereby acknowledge that I have read and agree to all the terms of this Agreement, and that I will act and perform my duties in the Clinical Trial in accordance therewith, and in accordance with my legal duties and responsibilities under all applicable law and MOH guidelines and instructions.

_____

Please complete full name

Responsible Pharmacist at the Hospital's pharmacy