CLINICAL TRIAL AGREEMENT

THIS AGREEMENT is made by and between King Faisal Specialist Hospital & Research Centre (Gen.Org.)-Jeddah Branch having an address at P O Box 40047, Jeddah 21499, Kingdom of Saudi Arabia and Dr. _____, Department of _____ (hereinafter jointly referred to as "KFSH&RC-J "), and _____, a corporation organized under the laws of _____, whose address is _____ (hereinafter called "SPONSOR").

All of the parties to this Agreement share a common mission of improving the public health by engaging in research for the purpose of discovering, and making available to the public, new and improved medical care, drugs and devices. In connection with this mission, SPONSOR desires to have further clinical research conducted on its (drug/device) described below. KFSH&RC-J having the expertise, facilities and opportunity, desire to conduct this research.

Description (drug/device):
_____
_____
_____

Now therefore, in consideration of the mutual covenants and promises herein contained, KFSH&RC and the SPONSOR agree as follows:

SECTION 1: STUDY PERFORMANCE

1.1 Protocol

KFSH&RC agrees to conduct to the extent funds are made available hereunder, a clinical study entitled "_____" (hereinafter referred to as "STUDY") in accordance with study protocol #:_____, as approved by the Institutional Review Board, a copy of which is attached hereto as Exhibit A. In the event of any conflict between Exhibit A and the provisions of this Agreement, the provisions of this Agreement shall govern.

1.2 Study Review

KFSH&RC-J shall conduct the Study at the KFSH&RC-J facilities with the prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all applicable federal, state and local laws and regulations. KFSH&RC-J shall provide SPONSOR with written evidence of review and approval of this Study by KFSH&RC-J Institutional Review Board ("IRB") prior to the initiation of the Study and shall inform SPONSOR of the IRB's continuing review promptly after such a review takes place, which shall be at least once per year.

1.3 Study Drug (Device)

SPONSOR shall provide KFSH&RC-J, at no charge, with quantities of the Study (Drug/Device) required for the Study. KFSH&RC shall safeguard such Study

(Drug/Device) with the degree of care used for its own property. Upon completion or termination the (Drug/Devise) will be disposed of in accordance with the related provisions of the approved protocol, otherwise upon SPONSOR's request, KFSH&RC-J shall return, or otherwise dispose of, any remaining Study (Drug/Device) in accordance with SPONSOR's instruction. KFSH&RC-J shall not use any Study (Drug/Device) for any purpose other than this Study, unless otherwise agreed in writing.

SECTION 2: STUDY RESULTS

2.1 Ownership of records, Data and Intellectual Property

SPONSOR shall own its case report forms and the data resulting from the Study. KFSH&RC-J shall own its medical records, research notebooks and related documentation and any intellectual property resulting from the Study subject to the option granted to SPONSOR to license Inventions in Section 2.3 below. KFSH&RC-J shall have the right to use the data for research, educational and patient care purposes, as well as to comply with any federal, state or local government laws or regulations. In recognition of SPONSOR's legitimate business interest in keeping unpublished research results from being made available to its commercial competitors, KFSH&RC-J agree not to knowingly:

(a) disclose the research results to third party commercial entities in a form or in sufficient detail suitable for use to obtain pre-marketing approval from the FDA prior to a publication of the Study; nor

(b) provide the case report forms to third party commercial entities.

Notwithstanding the above, SPONSOR shall not use any patient names, identifying information, photographs, or other likenesses without first obtaining the specific written informed consent of patient for such use.

2.2 Publication and Copyrights

(a) KFSH&RC-J shall be free to publish the results of the Study subject to the provisions of Section 3 below regarding SPONSOR's Proprietary Information. KFSH&RC-J shall furnish SPONSOR with a copy of any proposed publication for review and comment prior to submission for publication, at least thirty (30) days prior to submission for manuscripts and at least seven (7) days prior to submission for abstracts. At the expiration of such thirty (30) or seven (7) day period, KFSH&RC-J may proceed with submission for publication provided, however, that upon notice by SPONSOR that SPONSOR reasonably believes a patent application claiming and Invention (as defined in Section 2.3 below) should be filed prior to such publication, publication shall be delayed for an additional sixty (60) days or until any patent application(s) have been filed, whichever shall first occur. In no event shall the submission of publication of results be delayed for more than ninety (90) days for manuscripts and sixty-seven (67) days for abstracts from the date the publication/abstract was received by the SPONSOR. At the end of said period the KFSH&RC-J shall be free to publish the results as proposed.

(b) Neither party shall use the name of the other party or of any investigator in any advertising or promotional material without the prior written approval of the other.

KFSH&RC-J may, however, acknowledge SPONSOR's support for the Study in KFSH&RC's customary reports and publications and in any publications of Study results.

(c) If this is a multi-centre study, sponsor will furnish KFSH&RC-J with the data analysis of the entire study within six months of the termination of the study in case the multi-centre study results are not going to be published.

SECTION 3: CONFIDENTIALITY OF SPONSOR'S INFORMATION/MATERIAL

SPONSOR may wish, from time to time in connection with work contemplated under this agreement, to disclose confidential information to KFSH&RC-J personnel KFSH&RC-J agrees to make reasonable efforts to maintain the confidentiality of any proprietary information received from SPONSOR, which is designated in writing by SPONSOR as being confidential, for a period of _____ years from the date it is received, provided that this obligation shall not apply to any information which:

i) was already known to the KFSH&RC-J as evidenced by written records;

(ii) or later becomes publicly known under circumstances involving no breach of this agreement by KFSH&RC-J;

(iii) is lawfully disclosed to the KFSH&RC-J by a third party free of restrictions upon disclosure.

KFSH&RC shall ensure that Principal Investigator and other Research Staff and third parties are made subject to the obligations of confidentiality of this Agreement as indicated in Exhibit B attached and which is made part hereof.

The confidentiality obligations hereunder will not preclude disclosure pursuant to a valid subpoena, court order or requirements of applicable law.

SECTION 4: COMPENSATION

4.1 SPONSOR will support this Study with funding in the amount of SR_____ per evaluable patient, (totaling SR_____ for this study, based on _____ patients), payable to KFSH&RC-J as follows:

30% _____SR upon execution of this Agreement;

30% _____SR upon completion of _____ subjects;

30% _____SR upon completion of a total of _____ subjects

10% _____SR upon submission of all completed case reports.

For patients entered into the study, but subsequently dropping out, KFSH&RC-J will receive a pro-rata payment of SR_____ per patient as follows:

_____

_____
_____

4.2 Payments will be made in the name of KFSH&RC(Gen.Org.)- Jeddah Branch through electronic transfer to IBAN **SA6280000627608010300492**, Al Rajhi Bank, Khaldiah Branch, Jeddah, Kingdom of Saudi Arabia, attention: Dr. Jamal Zekri, Deputy Executive Director, Research Centre, KFSH&RC-Jeddah Branch.

SECTION 5: TERM AND TERMINATION

5.1 This Agreement shall be effective commencing on _____ and shall remain in effect until _____ unless sooner terminated as provided in this Article 2.

5.2 This Agreement may be terminated at any time by either party upon thirty (30) days prior written notice to the other;

5.3 Upon any termination hereof, the total funding amount set forth in Section 4.1 above will be appropriately pro-rated.

SECTION 6: LIABILITY/INSURANCE

6.1 SPONSOR shall defend, indemnify and hold harmless KFSH&RC-J, its affiliated hospitals, officers, employees, agents, successors, heirs and assigns of KFSH&RC-J (the "Indemnitees"), against any and all liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) that may be incurred by or imposed upon the Indemnitees, or any of them, in connection with any claim, suit, demand, action or judgment arising out of any side effect, adverse reaction, illness, or injury occurring to any person as a result of his or her involvement in the Study; as well as the following:

a) the design, production, manufacture, sale, use in commerce, lease, or promotion by SPONSOR or by an Affiliate or sub-licensee of SPONSOR of any product, process or service relating to or developed pursuant to this Agreement, or

b) any other activities to be carried out pursuant to this Agreement. SPONSOR's indemnification hereunder shall not apply to any liability, damage, loss or expense to the extent that it is attributable to:

(i) the negligence or willful misconduct of the Indemnitees, or,

(ii) a failure by Indemnitees to adhere to the terms of the protocol or SPONSOR's written instructions relative to use of the drug/device

6.2 KFSH&RC-J will perform the Study in accordance with generally accepted professional standards. EXCEPT AS SPECIFICALLY SET FORTH IN THIS AGREEMENT, KFSH&RC-J MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

6.3 KFSH&RC-J shall not be responsible or liable with respect to any subject matter of this Agreement under any contract, negligence, strict liability or other theory for any indirect, incidental, special or consequential damages including, but not limited to, loss of revenues and loss of profits.

6.4 KFSH&RC-J 's total liability for any cause of action arising in connection with this Agreement or the transactions contemplated by this Agreement, whether in a contract or in tort, including negligence or otherwise, shall be limited to the amount paid to KFSH&RC-J under this Agreement. SPONSOR waives and disclaims (and shall cause all its affiliates and licensees to waive and disclaim) any right to recover any damages in the aggregate in excess of such amount from KFSH&RC-J, including but not limited to any lost or anticipated profits or savings or any incidental, intangible, exemplary, punitive, special or consequential damages, regardless of the form of action, whether in contract or in tort, including negligence or otherwise and whether or not KFSH&RC-J was advised of the possibility or likelihood of such damages.

6.5 Commencing on the EFFECTIVE DATE, SPONSOR shall procure and shall maintain in full force and effect during the term of this Agreement comprehensive general liability insurance policies that protect and name the Indemnitees as additional names insured. Coverage shall be no less than sar_____ per incident and $_____ in annual aggregate. Coverage shall include broad form contractual liability for SPONSOR's indemnification obligations under this article 5.

6.6 SPONSOR warrants and represents that it will deliver promptly to KFSH&RC-J all necessary information and materials to enable KFSH&RC-J to provide the services hereunder and that all such information shall be accurate and complete and that KFSH&RC-J may rely on the accuracy and completeness of such information without undertaking any independent review or investigation thereof.

SECTION 7: INDEPENDENT CONTRACTOR

For the purpose of this Agreement and the conduct of the Study, KFSH&RC-J shall be, and shall be deemed to be, an independent contractor and the Principal Investigator and shall not be deemed to be agents or employees of the SPONSOR.

SECTION 8: GENERAL

8.1 This Agreement may not be assigned by either party without the prior written consent of the other party.

8.2 This Agreement including the protocol attached as Exhibit A, constitutes the entire and only agreement between the parties relating to the Study, and all prior negotiations, representations, agreements and understandings are superseded hereby. No agreements altering or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of the parties.

8.3 This Agreement shall be construed and enforced in accordance with the laws of the Kingdom of Saudi Arabia.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorised representatives.

KING FAISAL SPECIALIST HOSPITAL & RESEARCH CENTRE(General Organization) – JEDDAH BRANCH

By:_____ Date: _____
Name (Print): JAMAL ZEKRI, MD
Title: Deputy Executive Director, KFSH&RC(Gen.Org.)-Jeddah Branch

By: _____ Date: _____ Name (Print):
Title: Principal Investigator

SPONSOR
By: _____ Date: _____
Printed Name:
Title:

EXHIBIT B

CONFIDENTIALITY AND CERTIFICATION

I, _____ have read, understood and signed as Principal Investigator, the attached clinical trial agreement between KFSH&RC-J and _____ effective as of _____ ("the Agreement") and the Protocol referenced therein. I agree to comply with the terms of the Agreement and to cause all personnel working under my supervision to comply with its terms. I will take particular care to ensure compliance with the confidentiality provisions of the Agreement.

I also certify that I am not debarred under subsections 306(a) or(b) of the United States Federal Food, Drug and Cosmetic Act and that I have not and will not use, in any capacity, the services of any person debarred under such law with respect to services performed under this Agreement. I further certify that I will amend this certification as necessary in light of new information.

I will not, during the term of this Agreement, engage directly or indirectly in any work or undertakings with a third party which may conflict with my performance under this Agreement.

_____ _____

Principal Investigator: Date: