RESEARCH ADVISORY COUNCIL

INVESTIGATOR INITIATED STUDY CLINICAL TRIAL AGREEMENT

THIS AGREEMENT is made by and between [*name of principal investigator*], an individual who is a member of the staff of the King Faisal Specialist Hospital and Research Centre and eligible to serve as a principal investigator on research proposals submitted to the King Faisal Specialist Hospital and Research Centre's Research Advisory Council, whose address is Department of [*PI's department name*], MBC # [*PI's MBC #*], King Faisal Specialist Hospital & Research Centre, P.O. Box 3354, Riyadh 11211, Kingdom of Saudi Arabia (hereinafter referred to as "PI") and King Faisal Specialist Hospital & Research Centre having an address at P O Box 3354, Riyadh 11211, Kingdom of Saudi Arabia and, the King Faisal Specialist Hospital and Research Centre, an entity organized under the laws of the Kingdom of Saudi Arabia, whose address is P.O. Box 3354, Riyadh 11211, Kingdom of Saudi Arabia (hereinafter called "SPONSOR" or "KFSH," used interchangeably").

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 an intervention protocol (Exhibit A) and has supporting expertise, facilities, opportunity, and desire to conduct this research. PI has the expertise and desire to conduct this research on behalf and for the benefit of SPONSOR.

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

SECTION 1: STUDY PERFORMANCE

1.1 Protocol

PI and SPONSOR both agree to conduct, to the extent funds are made available hereunder, a clinical study entitled "[*title of the clinical trial study as submitted to the Research Advisory Council*]" (hereinafter referred to as "STUDY") in accordance with study protocol #: [*RAC #*], as approved by the Research Advisory Council, a copy of which is attached hereto as Exhibit A.

1.2 STUDY Review

The PI shall conduct the STUDY at the KFSH&RC facilities with the prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all applicable local laws and regulations. PI shall obtain approval of this STUDY from the KFSH&RC Research Ethics Committee ("REC") prior to initiation of the STUDY. Written evidence of review and approval of the STUDY by the KFSH&RC REC shall be maintained by PI and be made available to the Kingdom of Saudi Arabia's Food and Drug Authority upon request. Continuing review by REC shall take place at

least once per year, and documentation of continuing approval shall be maintained by PI.

1.3 STUDY Intervention

SPONSOR (i.e. KFSH&RC) shall provide for the STUDY, with the interventional materials required for the STUDY. PI shall safeguard such interventional materials with the degree of care used for his/her own property. Upon completion or termination, the interventional materials will be disposed of in accordance with the related provisions of the approved protocol. Otherwise, upon SPONSOR's request, PI shall return, or otherwise dispose of, any remaining STUDY interventional materials in accordance with SPONSOR's instruction. PI shall not use any STUDY interventional materials for any purpose other than this STUDY, unless otherwise agreed in writing.

SECTION 2: STUDY RESULTS AND CONFIDENTIALITY

2.1 Ownership of records, Data and Intellectual Property

All data and study documents related to the STUDY are owned by SPONSOR. PI shall have the right to use the data for research, educational and patient care purposes, as well as to comply with any local government laws or regulations.

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

2.2 Publication and Copyrights

Publications resulting from the STUDY should follow KFSH&RC publication policy.

2.3 Invention licensing and Intellectual Properties:
Any intellectual property created as a result of this STUDY is owned by the SPONSOR and its assigns and is subject to KFSH&RC Intellectual Property policy.

SECTION 3: FINANCIAL SUPPORT [*typically the figures here would all be zero*]

SPONSOR (i.e. KFSH&RC) will support this STUDY with funding in the amount of **SR ZERO** for this study, payable to an account specifically created for this clinical trial, monitored and audited by the Research Centre Central Financial Management Office. The provided funds will be used to support the budget included in the STUDY (Exhibit A).

SPONSOR will not remunerate PI for this STUDY in addition to PI's compensation as a KFSH employee.

SECTION 4: TERM

This Agreement shall be effective commencing on the date the STUDY protocol is approved by the KFSH&RC Research Advisory Council and shall remain in effect until the Final Report is accepted by the Research Advisory Council.

SECTION 5: PROFESSIONAL STANDARD OF CARE

By undertaking the STUDY and agreeing to be the Principal Investigator for the STUDY, PI represents that s/he possesses the requisite degree of learning, skill and ability necessary to undertake the required STUDY on behalf of SPONSOR in the highest professional manner. PI will exert his/her best judgment in the management of the STUDY entrusted to him/her by the SPONSOR, and will exercise all due care and diligence in the performance of his/her duties in accordance with the STUDY protocol.

SECTION 6: LIABILITY

6.1 KFSH&RC shall defend, indemnify and hold harmless PI, his/her participating research personnel, agents, successors, heirs and assigns of PI (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 KFSH&RC or by an Affiliate or sublicensee of KFSH&RC 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. KFSH&RC's indemnification hereunder shall not apply to any liability, damage, loss or expense to the extent that it is attributable to:

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

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

6.2 PI will perform the STUDY in accordance with generally accepted professional standards in clinical research.

6.3 PI 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 Commencing on the EFFECTIVE DATE, KFSH&RC 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 $_____ per incident and $_____ in annual aggregate. Coverage shall include broad form contractual liability for

KFSH&RC's indemnification obligations under this article 5.

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

SECTION 7: GENERAL

7.1 This Agreement may not be assigned by either party without the prior written consent of the other party. KFSH may assign or transfer this Agreement, without prior notice to PI, if substantially all its assets are assigned or transferred as part of the transformation project.

7.2 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.

7.3 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 authorized representatives.

KING FAISAL SPECIALIST HOSPITAL & RESEARCH CENTRE

By:_____ **Date: _____**

Name (printed)**: Riad El Fakih, MD**
Title: Head of Clinical Research Department
King Faisal Specialists Hospital & Research Centre

By: _____ **Date: _____**
Name (printed)**:**
Title: Principal Investigator
King Faisal Specialists Hospital & Research Centre

RESEARCH ADVISORY COUNCIL

EXHIBIT A

[*Attach KFSH&RC Research Ethics Committee approved research proposal together with budget.*]