KING FAISAL SPECIALIST HOSPITAL
AND RESEARCH CENTRE

RESEARCH ADVISORY COUNCIL (RAC)
PHARMACY INFORMATION LETTER

PROPOSAL TITLE:	
RAC NO.:	**PRINCIPAL INVESTIGATOR NAME:**

A. THIS PART IS TO BE COMPLETED BY THE PRINCIPAL INVESTIGATOR

1. PLEASE ITEMIZE ALL THE DRUGS THE STUDY SUBJECTS WILL RECEIVE INCLUDING DRUGS USED FOR ROUTINE MEDICAL CARE AND PLACEBO (ROU = ROUTINE MEDICAL CARE: EXP: = EXPERIMENTAL)
(If more space is needed, use copies of this form)

DRUG NAME										
	ROU	**EXP**	**ROU**	**EXP**	**ROU**	**EXP**	**ROU**	**EXP**	**ROU**	**EXP**
DOSE										
ADMINISTRATION ROUTE										
ADMINISTRATION FREQUENCY										
LENGTH OF TREATMENT										
DRUG STATUS *										
NUMBER OF PATIENTS										
PROVIDER: HOSPITAL OR SPONSOR (IDENTIFY SPONSOR)										
TOTAL DRUGS REQUIRED (PHARMACY WILL CALCULATE)										
(FOR PHARMACY USE) MEDICATION COST	**ROU:**	**EXP:**	**ROU:**	**EXP:**	**ROU:**	**EXP:**	**ROU:**	**EXP:**	**ROU:**	**EXP:**
RESEARCH PHARMACIST TIME					_____**(hrs) X**		_____**SR/hr**		**= SR** _____	

2. NAME OF RESPONSIBLE PERSON/ENTITY FOR RANDOMIZATION: *(in case if this is a randomized study)*

3. PERIOD OF TIME INTEND TO ACCRUE THE PATIENTS:

NOTE:
The Pharmacy must seek approval through the SFDA in order to import drugs. Approval of the proposal by the RAC does not guarantee that the drugs will be approved and/or released by the SFDA. Being a registered or investigational drug in any of the five reference countries (USA, Canada, UK, EMA, and Saudi Arabia) would help in obtaining SFDA approval.

Please use the following abbreviations: **HF** – on Hospital Formulary; **SFDA** – Saudi Food and Drug Authority; **USA** – registered in USA; **CA** – registered in Canada; **UK** – registered in UK; **EMA**– being approved by the European Medicines Agency; **USAI** – being investigated in USA; **CAI** – being investigated in Canada; **UKI** – being investigated in UK; **EMAI** – being investigated by EMA.

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PRINCIPAL INVESTIGATOR NAME:	**SIGNATURE:**	**DATE:**

B. THIS PART IS TO BE COMPLETED BY THE INVESTIGATIONAL DRUGH OFFICE: *(check appropriate boxes and complete)*

☐ The Pharmaceutical Care Division has assigned a Research Pharmacist to provide information and assistance in the conduct of this proposal. If you have any questions please call the Office of Research Affairs at EXT. NO. 32937.

The Pharmacy will provide the following: (Please make the numbering as tick boxes)

1. Drug keeping and dispending.
2. Preparation of Drug.
3. Drug Information (physician, nurse, pharmacist, etc.).
4. MOH Permit for import, release from Custom.
5. Patient counseling for drug information, compliance, medication handling, and return of unused products (if required).
6. Maintain and submit to RAC, upon completion/termination of the study, investigational drug records of:
   a. Inventory; delivery to KFSH&RC: Date, amount, lot No., expiration date, etc.
   b. Use by each study subject.
7. Follow the trial randomization procedure.
8. Supply the drugs listed on page 1 of this form.

☐ The Pharmacy will be happy to provide the above, provided the following issues have been satisfactorily addressed:

1.
2.
3.
4.

☐ The Pharmacy will not be able to assist with this project due to: ……..

……

……

☐ Total Pharmacy cost (routine care)**= SR** Total Pharmacy cost (experimental)**=** SR

COMPLETED BY:

NAME:	**SIGNATURE:**	**DATE:**

APPROVED BY DIRECTOR OF PHARMACEUTICAL CARE DIVISION:

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NAME:	SIGNATURE:	DATE: