مستشفى الملك فيصل التخصصي ومركز الأبحاث

King Faisal Specialist Hospital & Research Centre

Gen. Org. مؤسسة عامة

Jeddah Branch - فرع جدة

Institutional Review Board (IRB)

Application for Approval of Research Proposal

RESEARCH PROPOSAL PACKAGE

CONTENTS :

No.
Submission Date:

1. IRB RESEARCH PROPOSAL - COVER PAGE

Title of Proposal:	**Duration of Study:**

	Department or Affiliation	I.D. or Affiliation contact numbers	Position	* Signatures
Principal Investigator				
Co-Principal Investigator				
Other Co-Investigators				

(Please provide additional page if needed for additional co-investigators)

BUDGET	**Total**	**External Funding**	**Requested**

* Through their signatures, the investigators affirm that they will: 1) abide by the KFSH-IRB rules and regulations pertaining to the conduct of research; 2) adhere to the scientific protocol as outlined in the submission; 3) exhibit scientific rigor and integrity in the conduct of all phases of the research proposal; 4) include within the authorship, of any scientific articles arising from the research, only those individuals contributing significantly to that research as outlined in the "Guidelines for Manuscript Authorship"; and 5) declare any conflict of interest, or any accrual of financial gain, by virtue of association with the research.

APPROVAL		PROPOSAL		BUDGET		
		SIGNATURE	DATE	SIGNATURE	DATE	AMOUNT
	CHAIRMAN IRB					SR
	DEPUTY EXECUTIVE DIRECTOR, RESEARCH CENTRE					

2. DEPARTMENTAL APPROVAL

Title of Proposal:

Approval - Departmental Research Committee:
The Committee has reviewed this proposal and attests to its scientific validity.

Chairman (or Designee), Departmental Research Committee	Signature	Date

Approval - Department Head(s):
I have reviewed this proposal and approve the participation of the concerned personnel of my department in it.

PARTICIPANTS	DEPARTMENTAL CHAIRMAN /UNIT HEAD	SIGNATURE

Declaration of Conflict of Interest:

All investigators must declare any potential conflict of interest with respect to this research proposal. The presence of such conflict of interest must be explained (see below). The lack of such declaration by investigators involved with this proposal is taken as evidence of the absence of any conflict of interest.

Conflict of Interest:

NAME	SIGNATURE	EXPLANATION

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

3. ABSTRACT

Should not exceed 200 words and should include:

- *The importance of the research topic*
- *The research hypothesis, question or statement, specific objectives and the significance of the outcome*
- *<u>OUTLINE</u> the methods that will be used to accomplish the research specific objectives*

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

4. RESEARCH PROPOSAL

Title of Proposal:

Introduction

May include background information related to the research topic (Importance of the topic), the purpose in carrying out this research, and the importance of potential (expected) findings.

Methodology

May include: Inclusion Criteria and Exclusion Criteria, which will be used in selecting the research participants; Registration, Randomization Process, Data gathering methods, Procedures, Designated Central Laboratories, Follow-up, Safety and Efficacy Parameters, Expected Outcome, Sample Size, and Statistical Methods.

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

5. WORK PLAN AND RESPONSIBILITIES

Detailed description of the protocol work plan is mentioned in the original documentation. Please refer to the submitted documents. The following Table summarizes the job responsibilities of involved members:

Task	Investigator(s)

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

6. REFERENCES (comprehensive literature review)

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

7. BUDGET SHEET

PERSONNEL (NAME)	POSITION ON PROJECT	% TIME	GR/STEP	YEAR 1	YEAR 2
A) total for personnel:				SR	SR

EQUIPMENT *(use separate sheet if required)*	YEAR	
B) total for equipment:	SR	SR

SUPPLIES AND MATERIALS *(use separate sheet if required)*	YEAR	
C) Total for materials and supplies:	SR	SR

other expenses *(use separate sheet if required)*		AMOUNT	
category	purpose		
D) Total for other expenses:		SR	SR

TOTAL BUDGET (A ➔ D)	SR	SR

Suggested Sources of External Funding

Company	Address	Relationship to research proposal
None		

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

8. Pharmacy Information Sheet *(page 1 of 2)*

Title of the Proposal:

IRB #: (if available) _____ Principal Investigator: _____

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 If this is a randomized study, who is responsible for Randomization?

_____

3 Over what period of time do you intend to accrue the patients?

* The Pharmacy Department must seek approval through the MOH in order to import drugs. Approval of the proposal by the IRB does not guarantee that the drugs will be approved by the MOH. Being a registered or investigational drug in any of the five reference countries (USA, Canada, UK, Sweden, Saudi Arabia) would help in obtaining MOH approval.

Please use the following abbreviations: **HF** – on Hospital formulary; **MOH** – registered by the Saudi Ministry of Health; **USA** – registered in USA; **CA** – registered in Canada; **UK** – registered in UK; **SW** – registered in Sweden; **USAI** – being investigated in USA; **CAI** – being investigated in Canada; **UKI** – being investigated in UK; **SWI** – being investigated in Sweden.

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

PHARMACY INFORMATION SHEET (page 2 of 2)

Title of the Proposal: _____

_____

IRB#: (if available) _____ **Principal Investigator:** _____

This part is to be completed by the Pharmacy Department:
(Check (✓) appropriate box(es) and complete)

☐ The Pharmacy Department 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 the Institutional Review Board at extension 2984.

The Pharmacy department will provide the following:

I. Drug keeping and dispensing
II. Preparation of Drug
III. Drug Information (physician, nurse, pharmacist, *etc*)
IV. MOH permit for import, release from customs
V. Patient counseling for drug information, compliance, medication handling, and return of unused products (if required)
VI. Maintain and submit to IRB, upon completion/termination of the study, investigational drug records of:
    (a) inventory, delivery to KFSH&RC: Date, amount, lot #, expiration date, *etc.*
    (b) use by each study subject
VII. Follow the trial randomization procedure
VIII. Supply the drugs listed on page 1 of this form

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

1.
2.
3.

☐ The Pharmacy Department will not be able to assist with this project due to the following:

_____

_____

☐ Total Pharmaceutical cost (routine care) _____ *SR* Total Pharmaceutical cost (experimental) _____ *SR*

This form page completed by:

NAME (PRINT) _____ **SIGNATURE:** _____ **DATE:** _____

APPROVED BY: _____ **SIGNATURE:** _____ **DATE:** _____
(Head of Pharmacy Department)

9. BIOLOGICAL HAZARDS

Title of the Proposal:

Does the proposed research involve any toxic chemical?

1. **Please name chemicals and describe the nature of the hazard involved:**

_____

_____

2. **Does the proposed research involve any hazardous micro-organism?**

If yes, name the organisms and describe the nature of hazards expected.

_____

_____

Also describe facilities, safety measures and procedures to protect personnel and environment.

_____

_____

3. **Does the proposed research involve radioactive materials?**

If yes, describe the materials, half-life and methods of disposal and personnel protection.

_____

_____

4. **Does the proposed research involve recombinant DNA?**

If yes, are you familiar with NIH guidelines and do you have the containment facilities? _____

Describe the nature of genes to be cloned, organisms and plasmids to be used.

_____

_____

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____

10. Informed Consent

- ☐ for research involving the administration of drugs, use of devices or performance of procedures
- ☐ for research with no direct benefit to participant

Principal Investigator:

Name (print) _____ **Signature:** _____ **Date:** _____