



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  
Retrospective/Chart Review**

## **RESEARCH PROPOSAL PACKAGE**

### **CONTENTS:**

- 1. COVER SHEET**
- 2. DEPARTMENTAL APPROVAL FORM**
- 3. RESEARCH PROPOSAL**
- 4. LITERATURE REVIEW**

ANNEX A. DATA COLLECTION SHEET / CASE REPORT FORM

ANNEX B. CURRICULUM VITAE OF PRINCIPAL INVESTIGATORS

ANNEX C. HUMAN PARTICIPANT PROTECTIONS EDUCATION FOR RESEARCH TEAMS  
COMPLETION CERTIFICATE  
(FOR RESEARCHERS WHO HAVE NO PUBLISHED RESEARCH PAPERS YET)

**Principal Investigator:**

**Name (print)** \_\_\_\_\_ **Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**No.**

**Submission Date:**

# 1. IRB RESEARCH PROPOSAL - COVER PAGE

<b>Title of Proposal:</b>	<b>Duration of Study:</b>
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	Department or Affiliation	I.D. or Affiliation contact numbers	Position	* Signatures
<b>Principal Investigator</b>				
<b>Co-Principal Investigator</b>				
<b>Other Co-Investigators</b>				

\* 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
	<b>CHAIRMAN IRB</b>					SR
	<b>DEPUTY EXECUTIVE DIRECTOR, RESEARCH CENTRE</b>					

## 2. Departmental Approval

**Title of the Proposal:**

### Approval – Departmental Research Committee:

The Committee has reviewed this proposal and attests to its scientific validity.

<b>Chairman (or Designee), Departmental Research Committee</b>	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*
- *OUTLINE the methods that will be used to accomplish the research specific objectives*

**Principal Investigator:**

**Name (print)** \_\_\_\_\_ **Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

## 4. RESEARCH PROPOSAL

**Title of the 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; Sample Size, Data gathering methods, Expected Outcome 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:** \_\_\_\_\_