مستشفى الملك فيصل التخصصي ومركز الأبحاث
King Faisal Specialist Hospital & Research Centre
Gen. Org. مؤسسة عامة
Jeddah Branch - فرع جدة

Institutional Review Board

RESEARCH PROPOSAL: FINAL REPORT

Research Proposal IRB # _____

TITLE:

PRINCIPAL INVESTIGATOR(S): .....

.....

CO-INVESTIGATOR(S):

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APPROVAL DATE: .....

PROPOSED DURATION: .....

LAST PROGRESS REPORT DATE: .....

SPONSOR(S):

.....

.....

.....

COLLABORATOR(S)

.....

.....

.....

TOTAL BUDGET: .....

1 HAS THE RESEARCH PROPOSAL BEEN MODIFIED?

NO ☐ **Date of Modification:** _____

YES ☐ **Explain** **Date when the IRB was notified:** _____

◆

2 LIST OF THE OBJECTIVES OF THE RESEARCH PROPOSAL:

◆

3 SYNOPSIS OF MAIN RESULTS AND CONCLUSIONS

A. Did you encounter any problem? **NO** ☐ **YES** ☐ *Please list.*

◆

B. Were the objectives of the research achieved? **NO** ☐ **YES** ☐

If NO, which ones were not achieved? Why?

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4 PUBLICATIONS & RELATED ACTIVITIES, *WHICH HAVE ARISEN FROM THIS PROPOSAL:*

(Please list all presentations, abstracts, and publications. Please include a copy of any publication not previously submitted to the IRB.)

◆

5 DID YOU ADHERE TO THE IRB MANUSCRIPT AUTHORSHIP GUIDELINES REGARDING ALL PUBLICATIONS/ABSTRACTS RESULTING FROM THIS PROPOSAL?

(October 2004 update available at www.icmje.org and at the IRB Office)

YES ☐ **NO** ☐ **Explain.**

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6 CONFLICT OF INTEREST? WAS THERE AT ANY TIME DURING THE COURSE OF THIS INVESTIGATION ANY CONFLICT OF INTEREST PERTAINING TO ANY OF THE INVESTIGATORS?

YES ☐ **Explain.** **NO** ☐ **N/A** ☐

◆

FOR ALL RESEARCH STUDIES DIRECTLY INVOLVING HUMAN SUBJECTS:
(Human subject is defined as an individual about whom an investigator obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information).

7 HAVE YOU ADHERED TO THE GOOD CLINICAL PRACTICE GUIDELINES?
(copy available in IRB Office)

YES ☐ **NO** ☐ **Explain.**

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8 DID ANY SERIOUS OR UNEXPECTED ADVERSE EVENTS OCCUR?

YES ☐ **NO** ☐

If yes, list all serious and unexpected adverse events and the dates of submission to the IRB in Appendix A.

9 DID YOU MAINTAIN RECORDS OF PROPER INFORMED CONSENT FROM ALL STUDY SUBJECTS? *(Attach a copy of the consent form in current use)*

YES ☐

NO ☐ **Explain.**

◆

9.1 SUBJECT ENROLLMENT: (Appendix B)

9.1.1 How many were anticipated (original protocol)? _____

9.1.2 How many enrolled? _____

9.1.3 Did any withdrew? YES ☐ **NO** ☐

9.1.4 How many? _____

Why?

◆

10 IS THERE ANY NEW INFORMATION WHICH MAY AFFECT THE BENEFIT/RISK RATIO OF THE RESEARCH STUDY?

YES ☐ **Explain.** **NO** ☐ **N/A** ☐

SIGNATURE PRINCIPAL INVESTIGATOR: _____ DATE: _____

FOR ALL RESEARCH STUDIES INVOLVING LIVE VERTEBRATE ANIMALS:

11 HAVE YOU FULLY ADHERED TO THE IRB APPROVED PROPOSAL?

NO ☐ Explain. YES ☐

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12 HAVE YOU FULLY ADHERED TO THE INTERNATIONAL GUIDELINES FOR THE CARE & USE OF LABORATORY ANIMALS?

(Guidelines available at www.fbresearch.org and in the IRB office)

NO ☐ Explain YES ☐

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13 SPECIES & NUMBER OF ANIMALS

Species/ Strain	Age Range	Sex		No. Used	Total No. Approved
		M	*F*		

SIGNATURE PRINCIPAL INVESTIGATOR: _____ DATE: _____

HUMAN SUBJECT SERIOUS ADVERSE EVENTS and/or UNEXPECTED ADVERSE EVENTS REPORT

1. **Serious Adverse Event** means any adverse experience that results in any of the following outcomes: death, a life-threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

   (Important medical events that may not result in death, be life-threatening or require hospitalization may be considered a serious adverse event when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.)

   Unexpected Adverse Event is any adverse experience associated with the study article for which the specificity or severity is not consistent with the current investigator brochure, or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described elsewhere in the current application. "Unexpected" refers to an adverse drug experience that has not been previously observed.

2. List subjects by identifiers and adverse events.
   Characterize the adverse events as to:
   a. Severity – Grade 3, Grade 4, Grade 5
   b. Recovery - total, partial, none
   c. Relationship to protocol - none, possible, probable, definite *(based on the opinion of the principal investigator)*

IDENTIFIER	Adverse Event	Severity of Event	Is it expected?	Recovery from Event	Relationship to Protocol	Date submitted to the IRB

HUMAN SUBJECT ENROLLMENT FORM

Cumulative number of subjects enrolled during the duration of the Project:

Dates: From: _____ To: _____

List the identifiers of all human subjects enrolled at KFSH&RC-J during the duration of the Project.
