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

Institutional Review Board

BIANNUAL PROGRESS REPORT

Research Proposal IRB # _____

TITLE:

A. HAVE THERE BEEN ANY CHANGES IN THE FOLLOWING? (If yes please specify):

Research start date: _____

Category		Yes	No	Specify /Explain
1.	**Protocol Title**			
2.	**Investigators**			
3.	**Participating Centers**			
4.	**Working Hypothesis**			
5.	**Methodology**			
	5.1 Sample size			

Category		Yes	No	Specify /Explain
	5.2 Start and End dates			
	5.3 Randomization *(if applicable)*			
	5.4 Involvement of vulnerable patients and additional safeguards *(if applicable)*			
	5.5 Inclusion Criteria			
	5.6 Exclusion Criteria			
	5.7 Questionnaire or investigative instruments, if any			
	5.8 Statistical Analysis			
6.	**Consent Form**			
	6.1 Expiry Date			
7.	**Budget**			
	7.1 Use of hospital services			
	7.1.1 Laboratory			
	7.1.2 Imaging Studies			
	7.1.3 Pharmacy ***(Plan for drug safety monitoring if applicable)***			
	7.2 Others			
8.	**Further Explanation**			
	Category #:			

B. SUBJECT ENROLLMENT:

How many were anticipated (original protocol)? _____

How many enrolled since last Biannual Report? _____

How many now totally enrolled? _____

C. OVERALL PROGRESS OF RESEARCH:

1. **Are you reasonably on schedule with the progress of the research?** ☐ **YES** ☐ **NO**

   If NO, why?

   ☐ **Late start? Explain.** _____

   ☐ **Slow recruitment? Explain.** _____

   ☐ **Methodological difficulty? Explain.** _____

   ☐ **Other?** _____

2. **Do you think you will require more than the anticipated time?** ☐ **YES** ☐ **NO** ☐ **Maybe**

D. CONFLICT OF INTEREST:

Do you, or your research colleagues, have any conflict of interest relating to this proposal? ☐ **YES** ☐ **NO** **If yes, explain**

_____

_____

Completed by: _____ **Date:** _____

Principal Investigator's Signature: _____ **Date:** _____

APPENDIX A

HUMAN SUBJECT ENROLLMENT FORM

Cumulative number of subjects enrolled during the dates indicated:

Dates: From: _____ **To:** _____

List the identifiers of all human subjects enrolled at KFSH&RC-J during this Biannual Progress Report.

APPENDIX B

HUMAN SUBJECT ADVERSE EVENTS REPORT

1. 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