RESEARCH ADVISORY COUNCIL

RESEARCH PROPOSAL FINAL REPORT

RAC

Sponsor/Collaborator # :

TITLE:

CURRENT PRINCIPAL INVESTIGATOR(S):

CURRENT CO-INVESTIGATOR(S):

APPROVAL DATE:

PROPOSED DURATION:
APPROVING COMMITTEE(S):
LAST PROGRESS REPORT DATE:

NUMBER OF PROGRESS REPORTS:

SPONSOR /COLLABORATOR(S):
TOTAL BUDGET:
SOURCE OF FUNDS:
ACCUMULATIVE AMOUNT BILLED:
ACCUMULATIVE AMOUNT RECEIVED:

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1 HAS THE RESEARCH PROPOSAL BEEN MODIFIED?

No ☐
Yes ☐ **Explain**

2 HAVE THE INVESTIGATORS CHANGED?

No ☐

Yes ☐ **Explain**

3 APPROVED AIMS OF THE RESEARCH PROPOSAL:

4 SYNOPSIS OF MAIN RESULTS AND CONCLUSIONS

(Please provide sufficient information to evaluate the project. Refer to previous reports or publications as necessary)

In your opinion, how successful was the project? ___ /5

Did you encounter any problem? **No** ☐ **Yes** ☐ Please list.

What percentage of the project aims was accomplished? ___ %

5 PUBLICATIONS & RELATED ACTIVITIES:

(Please list all presentations, abstracts, and publications which are related to this proposal. Please include a copy of any publication not previously submitted to the Research Advisory Council. Mark with an asterisk the publications that have been listed in progress or final reports of other proposals).

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

(N Eng J Med 1997; 336:309-315)

Yes ☐ **Not applicable** ☐

No ☐ **Explain**

7 DO THE INVESTIGATORS WISH TO PURSUE THE SAME LINE OF RESEARCH IN THE FUTURE?

Yes ☐ **Explain**

No ☐ **Explain**

FOR ALL RESEARCH STUDIES 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).

8 HAVE YOU FULLY ADHERED TO THE GOOD CLINICAL PRACTICE GUIDELINES ?
(copy available in RAC Office)

Yes ☐
No ☐ Explain

9 DID ANY ADVERSE EVENTS OCCUR?
(Any untoward or unfavourable occurrence experienced by a subject participating in a clinical study)

No ☐
Yes ☐ If yes, the attached Human Subject Adverse Event Report must be completed.

Were they expected?	Were they serious?
No ☐	No ☐
Yes ☐	Yes ☐

10 DID YOU OBTAIN AND MAINTAIN RECORDS OF PROPER INFORMED CONSENT FROM ALL STUDY SUBJECTS?

Yes ☐
No ☐ Explain

(attach a copy of the consent form in current use)

11 HOW MANY SUBJECTS HAVE BEEN ENROLLED? ____
(Please complete the attached Human Subject Enrollment Report)

12 HOW MANY ENROLLED SUBJECTS WITHDREW? ____
List reasons for withdrawal:

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

No ☐
Yes ☐ Explain

Signature Principal Investigator: _____ Date: _____

HUMAN SUBJECT ADVERSE EVENT REPORT

1. An adverse event is defined as any untoward or unfavorable occurence experienced by a subject participating in a clinical study. List each type of adverse events observed during the conduct of the study (*ie,* headache, rash, social or psychological stress, loss of privacy, break of confidentiality). Mark by an asterix, adverse events observed in other centers (if this is a multi-center study).

2. List subjects by medical record number (MRN) and adverse events. Numeric identifiers or initials are acceptable only in the absence of MRN. Characterize the adverse events as to:
   a. Severity - mild, moderate, severe
   b. Recovery - total, partial, none
   c. Relationship to protocol - none, possible, probable, definite

MRN	Adverse Event	Severity of Event	Recovery from Event	Relationship to Protocol

HUMAN SUBJECT ENROLLMENT FORM

1. Cumulative number of subjects enrolled during lifetime of the Project

   Dates: From: To:

2. Number of subjects enrolled during last approval year:

   Dates: From: To:

   List the MRN # (numeric identifiers or initials are acceptable only in the absence of a MRN) of all human subjects enrolled at KFSH&RC during lifetime of the Project. Identify human subjects enrolled in the last approved year by an asterix, using additional pages if necessary.
