RESEARCH ADVISORY COUNCIL

GUIDELINES FOR SUBMISSION OF A RESEARCH PROPOSAL

I Plan your application carefully before you commence writing.

II Establish deadlines for the preparation of the proposal. This is particularly important in collaborative investigations.

III Write your proposal according to the following format. Use basic English, avoid jargon and spell out acronyms when used initially. Number all pages consecutively beginning with the abstract of the proposal and continuing to the last page of references.

IV Have your proposal reviewed and proof-read by an objective colleague whenever possible. More often than not, the colleague will draw your attention to some minor points in your proposal that you may have overlooked.

V If an Investigator wishes to participate in a multi-centre study which has been initiated and previously approved by an acknowledged academic, medical or research institution, he/she can submit a copy of that proposal, and indicate the exact contribution/involvement of KFSH&RC in the cover letter. Such proposals may be eligible for an expedited review. (See "Guidelines for an Expedited Review").

VI The Principal Investigator (PI) should submit the proposal with all relevant forms completed,and a covering memo, through the PI's Department Chairman or Head, to the Chairman of the Research Advisory Council, MBC 03, Research Centre, Room 304.

The Office of Research Affairs (ORA) screens the proposals for compliance with submission guidelines, forwards them for peer review (if indicated) and sends them to the appropriate Research Committee(s) for evaluation. Only complete submissions will be processed. Incomplete submissions will be returned to the PI. The PI will be informed of the receipt of the complete proposal by the ORA and will be contacted if the Committee(s) requires clarification or recommends modification. The final decision will be communicated to the PI by the ORA.

PROPOSAL FORMAT

1 COVER PAGE

Indicate the expected duration of the study from the time of approval until the time of submission of final report. Enter the name of potential sponsor(s)/collaborator(s). In the event of more than one Principal Investigator, please indicate which one is the primary contact. (check guidelines for proposal authorship).

2 ABSTRACT

The abstract is an important part of the application. It summarises your whole proposal, and it may be utilised in various communications regarding research activity of the Institution. It should include a brief background, specific aims, methodology, significance, and a description of how your results may affect the contention in the research area. Recommended length is 200 words.

3 INTRODUCTION

This should encompass a review of the literature relevant to the proposed study including the following:

a) What has already been accomplished in the field.
b) What is the rationale behind your study? Why is it worth doing?
c) Brief description of your proposed study.
d) What gaps would the study fill in the area of investigation?
e) What relevant work has been done by the Investigators (or others) to indicate the expected productivity of the proposal?
f) Provide preliminary data, if any.
g) The expected benefits and adverse effects to patients, if applicable.

Recommended length is 2-4 pages.

4 CLEAR STATEMENT OF THE HYPOTHESIS AND/OR AIM(S) OF YOUR STUDY

The statement of each aim should be clear, concise, and exact.

5 METHODS

Describe clearly (provide references where applicable):

a) The experimental design.
b) On-site established methods and new methods, if any.
c) The procedure for data collection and analysis. (assistance may be available through Biostatistics, Epidemiology, and Scientific Computing Department)
d) Potential difficulties and limitations of the methods to be used, and ways by which these difficulties can be resolved.

If the proposal is examining a **BASIC** biomedical science question, please proceed to Item 6, STATISTICAL CONSIDERATIONS.

If the proposal is examining a **CLINICAL** question, information requested in points (e) or (f) must be included before proceeding to Item 6, STATISTICAL CONSIDERATIONS.

e) For interventional trials of drugs, devices, or procedures, the following information should be included:
- The study design, eg, open, controlled, placebo-controlled, crossover; and phase, eg, phase I, II, or III or IV.
- A clearly defined method for patient recruitment including advertisement, if any, and clear criteria for including and excluding patients.
- A bias free method for assigning patients to the study treatments (usually randomisation), if appropriate.
- A clear specification of the test and control interventions; if the study is a drug trial, give clinical trial dosage, duration of therapy, and adjunctive therapy, if any.
- Clearly defined outcome measures to be used for treatment comparisons.
- Specification of the required length of patient follow-up.
- Flow sheets for monitoring therapeutic progress and adverse effects.
- Data collection sheets for documentation of therapeutic progress (ie, evaluation parameters) and adverse effects of the proposed activity.
- Guidelines for stopping the study, if appropriate.

f) If the proposal is a diagnostic test assessment then it should include:
- An independent, blind comparison with a reference standard.
- Consideration of inclusion of an appropriate spectrum of patients to whom the diagnostic test will be applied in clinical practice.

6 STATISTICAL CONSIDERATIONS

a) Describe methods of statistical analysis. State the reason for choosing such methods. If analysis is computer aided, state the name and source of the software used.

If the proposal is **BASIC**, proceed to Item 7, Ethical considerations/Consent form

b) For interventional trials of drugs, devices or procedures include:
- Number of patients; considerations of sample size and assumptions used in calculating sample size based on clearly defined expected outcomes.
- Planned statistical analysis.
- Plan for analysis of dropouts, crossover, and poor compliance, if applicable.
- Plan for interim analysis, if any.

c) For Diagnostic test assessment include:
- Consideration of pre-test and post-test likelihood, as well as sensitivity and specificity.
- Consider intra and inter observer variation, if appropriate.

7 ETHICAL CONSIDERATIONS/CONSENT DOCUMENTS

a) indicate the number of subjects to be enrolled at KFSH&RC and the total number to be enrolled in the study (if multi-centre study);
b) indicate the characteristics of the study population (gender, age range, racial and ethnic groups) and justify any exclusion of specific gender, age, and racial or ethnic groups;
c) indicate the inclusion and exclusion criteria and whether vulnerable subjects will be involved (ie, subjects with diminished mental capacity, children, pregnant women, foetuses, economically or socially deprived subjects, prisoners) and if so, what are the special

precautions that will be taken to ensure that the consent is freely given and that the rights and welfare of the subjects are protected (eg, assent from children);

d) indicate where and how research data will be stored to ensure confidentiality, and who will have access to information about the subjects that is identifiable;

e) indicate how subjects will be identified and recruited for participation in the study, when and where consent will be obtained, and how you will determine whether the subjects (or their surrogates) understand the information that is provided in the consent document;

f) indicate whether the study will include medical record review (hard copy or via computer) and if so, list those individuals (eg, co-investigators, Fellows, research nurses, research co-ordinators, pharmaceutical company protocol monitors, etc) who require access to the record;

g) Summarise what will actually be done to the subjects during their participation in the study. Make certain that the following is included:

    a) a clear description of what is being done for research purposes and what is being done as part of standard clinical care;
    b) a list of tests and procedures that will be performed for research purposes (eg, blood tests, urine tests, cultures, interviews, questionnaires, surgical procedures, cardiac catheterisation, pulmonary function tests, X-rays, scans, etc);
    c) a brief description of the analyses that will be performed on the biologic or non-biologic (ie questionnaires) samples collected;
    d) a list of investigational drugs that will be administered;
    e) a list of investigational devices that will be used;
    f) a statement that defines who will be financially responsible for the costs associated with participation in the study (eg, travel, examinations, procedures, drugs, devices, etc), and a statement that defines what will be provided without cost to the subjects;

h) The general rule is that research involving human subjects requires a documented (written) informed consent (in Arabic and English). 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.

The consent document must include "basic elements" and when applicable "additional elements" (see check-list for consent documents for investigators, REC Members, and Staff; and guidelines for consent documents). The Research Advisory Council may approve a waiver of signed informed consent or a waiver of informed consent (see request for modification in documentation of informed consent and request for modification of informed consent). A copy of the consent form should be given to the research subject (or surrogate), a copy should be kept in the medical record of the research subject and the original should be kept with the Principal Investigator. The signature of at least one parent or guardian, or more, depending on the risk, is required for children under 18 years-of-age to participate in the study. In addition, elementary school age children may provide oral assent (see certification of assent of minors), and middle school age children may provide a written assent (cosign the consent form). A witness signature on the consent form is only needed when the subject or the subject's guardian cannot read.

8 ORGANISATION & MANAGEMENT (WORK PLAN)

Describe early and precisely

a) The work plan including timetable of events

b) the role and responsibilities of the persons involved in the study.

9 REFERENCES

Number references consecutively, in the order in which they are first mentioned in the text. A numbered list of complete references, in order of appearance, should be included here. Suggested citation style (for biomedical articles) is as follows:

You CH, Lee KY, Chey RY, Menguy R. Electrogastrographic study of patients with unexplained nausea, bloating and vomiting. Gastroenterology 1980 Aug;79:311-4.

10 INVESTIGATORS ASSURANCE FORM

Must be completed and signed by each Investigator.

11 BUDGET

Complete the Budget Form as comprehensively as possible. Write N/A if not applicable. The information included is needed to negotiate agreements with external sponsors as well as to process and to evaluate the proposal.

12 CURRICULUM VITAE

The Curriculum Vitae of the Principal Investigator(s) must be included. Co-Investigators should provide a short biographical sketch and a list of their relevant publications for the past five years (use the Co-investigator CV Summary Form).

13 PROPOSAL CLEARANCES FORM

If part of the study involves department(s) other than the department of the submitting investigator, a clearance (signature) from the Chairman of each such department should be obtained. Involvement includes personnel, facilities, equipment, etc.

14 PHARMACY INFORMATION LETTER

If drugs will be used, this form must be completed by the Principal Investigator and signed by the Head of Pharmacy Services.

15 BIOLOGICAL, CHEMICAL AND RADIOLOGICAL HAZARDS FORM

Complete and sign.

16 ANIMAL CARE & USE FORM

If you are planning to use animals in your proposed research, completion of an Animal Care & Use Form and budget is required. The ORA will forward the form to the Animal Care & Use Committee (ACUC).

17 SUGGESTED REVIEWERS (OPTIONAL)

Please provide the names and means of contact of 3-5 people external to the King Faisal Specialist

Hospital & Research Centre who would be able and willing to provide a knowledgeable review of this proposal. You may also suggest the names of the reviewers to whom you would not like this proposal sent. The selection of the reviewers is at the discretion of the Research Advisory Council.

NOTES

Investigators should be aware that if the proposal is approved, it is required that a Progress Report is submitted annually to the ORA (or more frequently if so requested by the RAC). Failure to do so will result in suspension/termination of the study by the RAC. Also, on completion (or discontinuation) of the project, a Final Report must be submitted to the ORA .

Any publications resulting from the proposal should state the proposal number in the acknowledgements. Any publications (including abstracts) should be registered/cleared by the RAC before submission. The RAC currently cover costs of page charges and reprints for all RAC approved proposals. In the event the PI leaves the Institution, or is unable to continue the study, a suitable replacement, fulfilling the criteria for proposal authorship, should be nominated by the departing PI and approved by his/her Department Chairman and the RAC.