

# RESEARCH ADVISORY COUNCIL

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## GUIDELINES FOR EXPEDITED REVIEWS

### I Proposals that originate from KFSH&RC

#### 1.0 Purpose of the Proposal

- 1.1 to obtain preliminary data needed to develop hypotheses and/or experimental design for a fully-fledged research proposal; or
- 1.2 retrospective review of the data, such as, medical records reviews, case reports, re-analysing data; or
- 1.3 extension of RAC approved proposals into related areas, such as, studying the TSH receptor gene for mutations in a particular thyroid cancer patient as an extension of an RAC approved proposal on the TSH receptor gene or studying p53 mutations in a particular cancer patient as an extension of an RAC approved proposal on cell cycle abnormalities.

#### 2.0 Limits

- 2.1 the duration, including complete data analysis, is less than 12 months from approval date,
- 2.2 the cost to the Institution, including materials and new equipment, is less than 20,000 Saudi Riyals,
- 2.3 the total personnel commitment should not exceed 0.25 full time equivalents (FTE),
- 2.4 the commitment of each and any investigator should not exceed three concurrent expedited proposals,
- 2.5 proposals involving human subjects or vertebrate animals, should fulfil the criteria for expedited review by the Research Ethics Committee (REC) or the Animal Care & Use Committee (ACUC),
- 2.6 the current proposal must not adversely affect other duties of the investigators, and
- 2.7 the current proposal must not adversely affect other RAC approved proposals.

### II Proposals that originate outside KFSH&RC

- 1.0 Proposals which have been approved by a body equivalent to RAC and are performed at KFSH&RC in collaboration with other centres, can be subjected to an expedited review. These include pharmaceutical company-sponsored proposals, non-profit funding agency-sponsored proposals, and multi-centre proposals.

#### 2.0 Limits

- 2.1 the cost to KFSH&RC, including materials and new equipment, should not exceed 20,000 Saudi Riyals for non-profit funding agency-sponsored proposals,

- 2.2 the total personnel commitment should not exceed 0.25 FTE for non-profit funding agency-sponsored proposals,
- 2.3 for industry-sponsored proposals, a contribution from the sponsor that exceeds the cost of the proposal to KFSH&RC should be made to the RAC research funds,
- 2.4 the approval will be granted for an initial period of 12 months. Renewal will be based on satisfactory progress and justification,
- 2.5 the commitment of each and any investigators should not exceed three concurrent expedited proposals,
- 2.6 proposals involving human subjects and vertebrate animals should fulfil the criteria for expedited review by the REC and ACUC,
- 2.7 the current proposal must not adversely affect other duties of the investigators,
- 2.8 the current proposal must not adversely affect other RAC approved proposals, and
- 2.9 a formal letter of approval by a research advisory body, equivalent to the RAC (subject to acceptance by the RAC) should be provided with the application. Comments of previous reviewers should also be provided when possible.

### **III Application Instructions**

The 'Guidelines for Submission of a Research Proposal' should be followed, including submission of all applicable forms. However, the following sections; abstract, introduction, specific aim/hypothesis, design and methods and references should be as concise as possible. For proposals which originate outside KFSH&RC, the exact contribution of KFSH&RC should be specified and the original proposal should be attached.

### **IV Review Process**

The Principal Investigator (or KFSH&RC Primary Investigator for proposals under II above) should indicate in the covering letter his/her desire, that the proposal be submitted to expedited review. The proposal is reviewed by the Proposal Processing Section within two working days to determine whether it fulfils the criteria for expedited review. If so, the proposal is submitted to the Chairmen of the appropriate RAC supporting Committees (CRC, BRC, REC, and ACUC). The assigned RAC Committee Chairmen will personally review (or assign a reviewer from their committee) the scientific merits and ethics of the proposal (as applicable) and make their recommendation within 10 working days. The recommendation can be either;

- 1.0 Approve the proposal as submitted, or
- 2.0 Conditionally approve the proposal, or
- 3.0 Obtain further information, or
- 4.0 Submit the proposal to the full Committee for review.
- 5.0 Submit the proposal to external reviewers and the full Committee for review (for CRC and BRC).

Once the proposal is approved, the approval is announced at the next meeting of the appropriate Committee(s). The proposal should be available for Committee Members to review if they wish to do so.