

Research Regulations at the King Faisal Specialist Hospital and Research Centre (KFSH & RC) – Riyadh, Saudi Arabia

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Abstract: The King Faisal Specialist Hospital and Research Center (KFSH&RC) is one of the leading healthcare institutions in the Kingdom of Saudi Arabia and Joint Commission International (JCI)-accredited academic medical facility. KFSH&RC is the national referral center for Oncology, Organ Transplantation, Cardiovascular Diseases, Neurosciences and Genetic Diseases. The Research Centre focuses on basic and translational research primarily in cancer, stem cell therapy, cardiovascular diseases, transplant immunology, genetics, molecular diagnostics and proteomics. The Research Advisory Council (RAC) of the KFSH & RC promotes, regulates, and monitors all aspects of Research activities undertaken by members of, or within the KFSH & RC and affiliated institutions. It is dedicated to promoting clinical and biomedical research of the highest technical and scientific caliber that examines relevant questions and ensures that research at the KFSH & RC meets locally and globally accepted ethical and safety standards and that research resources at KFSH & RC are optimally utilized. The RAC is supported by five standing committees: the Research Ethics Committee (REC), the Clinical Research Committee (CRC), the Basic Research Committee (BRC), the Animal Care and Use Committee (ACUC) and the Recombinant DNA Committee (RDC); an International Advisory Board (IAB); and the Office of Research Affairs (ORA). The ORA coordinates the activities of, and provide support to the RAC, obtain and administer external research funds for KFSH & RC investigators and protect the interests of KFSH & RC and its investigators, protect the inventions made at KFSH & RC and help commercialize research results, ensures compliance of research activities at KFSH & RC with applicable policies and provide assurance of KFSH & RC compliance to regulatory policies and provides information to professionals and the public on the research activities at KFSH & RC and on global scientific discoveries.

Keywords: KFSH&RC, research regulations, Ethics Committee.

INTRODUCTION

The Research Advisory Council

The Research Advisory Council (RAC) promotes, regulates, and monitors all aspects of the research activities undertaken by members of, or within, the King Faisal Specialist Hospital & Research Centre (KFSH&RC) and affiliated institutions. The RAC Executive Council meets on a bi-monthly basis or as frequently as required.

The RAC is responsible for

1. providing the Chief Executive Director (CED) with:
 - recommendations on strategic planning for all research activities.
 - recommendations on the development and allocation of all research resources.
 - recommendations on regulation of all research activities.
 - an annual report of all research activities.
 - review of other research related subject matters as referred by the CED

2. promoting clinical and biomedical research that is of high scientific and ethical caliber and is relevant to the KFSH&RC and the Kingdom of Saudi Arabia by:
 - collaborating with national and international institutions,
 - raising research funds, and
 - enhancing awareness of research importance and implications

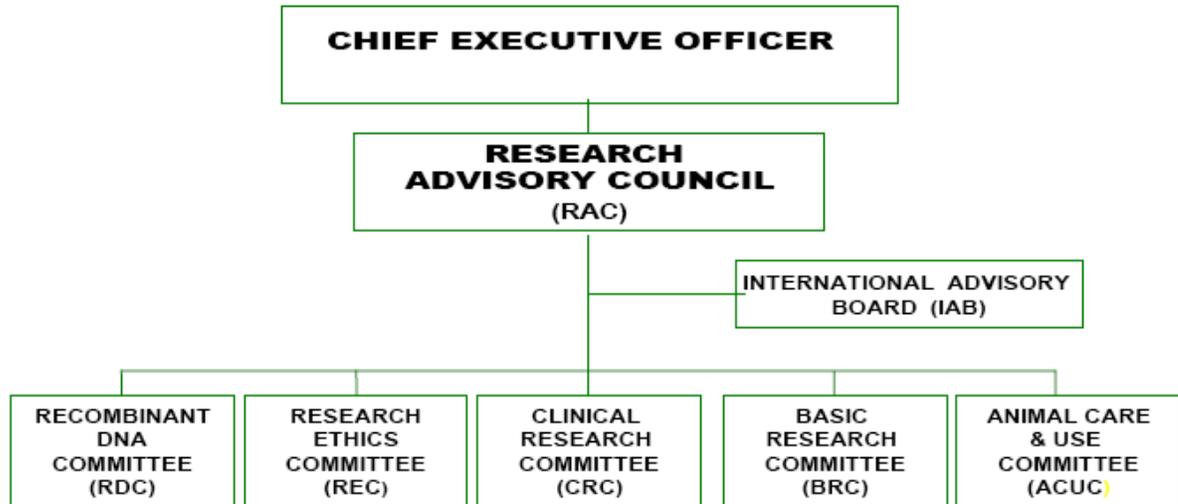
- collaborating with national and international institutions,
- raising research funds, and
- enhancing awareness of research importance and implications

3. objectively evaluating, approving, and monitoring all research activities undertaken by members of, or within, the KFSH&RC. Research is defined as any systematic investigation (i.e., the gathering and analysis of information) designed, in whole or in part, to develop or contribute to generalizable knowledge. Proposals and activities not approved by the REC, ACUC, or RDC cannot be approved by the RAC.

Accountabilities of the RAC

1. ensuring that the safety, welfare, autonomy, and rights of human subjects involved in research are well protected.
2. ensuring that the use of animals in research is consistent with national and international standards, such as the Guide for the Care & Use of Laboratory Animals, National Research Council, USA.

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Table 1. Organizational Structure of the Research Advisory Council

3. ensuring that the use of microbiological agents and recombinant DNA molecules in research is safe and consistent with national and international standards, such as the NIH Guidelines for Research Involving Recombinant DNA Molecules.
4. ensuring that internal and external research resources are used most efficiently and on relevant research studies.
5. reviewing and approving for submission all scientific and medical manuscripts and abstracts authored by members in order to protect the public image and financial interest of KFSH&RC.
6. making recommendations to the CED on other research matters such as misconduct in research, dispute on authorship, conflict of interest, and intellectual property.

The RAC Executive Committee is composed of

Chairman, Research Advisory Council

Co-Chairman, Research Advisory Council

Members

Co-Director, Office of Research Affairs	Coordinator
Executive Director, Medical and Clinical Affairs	Member
Executive Director, KFSH&RC (Gen. Org) Jeddah Branch	Member
Three (3) Chairmen/Consultants, Medical and Clinical Affairs	Member
Three (3) Chairmen/Scientists, Research Centre	Member
Chairman, Recombinant DNA Committee	Member
Executive Director/Deputy Executive Director, Academic and Training Affairs	Member

In order to fulfill its mandate, the RAC meets on a bi-monthly basis.

The RAC Supporting Committees

A. The Research Ethics Committee (REC)

1. The REC is the Institutional Review Board and holds its regular meetings twice a month or frequently as required. It is charged to evaluate the religious and ethical aspects of all research proposals involving human subjects that are undertaken by members of, or within, the KFSH&RC; recommended proposals may be subject to further review and disapproval by the RAC. 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 (e.g., medical record).
2. The REC depends on the recommendations of the CRC or BRC regarding the scientific aspects of proposals under its review.
3. The REC evaluates the proposals according to nationally and internationally accepted ethical criteria, to ensure that: a) the safety, welfare, and rights of the human subjects are adequately protected; b) when appropriate, an informed consent, within the best definition of that term, may be obtained from the subjects; and c) the risks to subjects are minimized and are acceptable when measured against the possible benefits of the study.
4. The REC assists the RAC in formulating strategic research planning and policies to regulate research within the KFSH&RC and evaluates other ethical issues related to research when referred by the Chairman of the RAC.

B. The Clinical Research Committee (CRC)

1. The CRC meets on a bi-weekly basis or as required and is charged to evaluate the scientific aspects of all research proposals of clinical nature that are undertaken by members of, or within, KFSH&RC. Proposals of clinical nature include human interventional studies, interview/ questionnaire

- studies, and retrospective medical records review studies.
- The CRC evaluates the proposals for scientific merit, feasibility, relevance to KFSH&RC and the Kingdom, and validity of design and methods.
 - The CRC assists the RAC in formulating strategic research planning and policies regulating research within the KFSH&RC as well as in establishing priorities and allocating research funds.

C. The Basic Research Committee (BRC)

- The BRC meets on a bi-weekly basis or as required and is charged to evaluate the scientific aspects of all research proposals of basic nature that are undertaken by members of, or within, KFSH&RC. Proposals of basic nature include proposals that are conducted on animals or tissue cultures or that are based on basic science questions even if performed on materials obtained from human subjects.
- The BRC evaluates the proposals for scientific merit, feasibility, relevance to KFSH&RC and the Kingdom, and validity of design and methods.
- The BRC assists the RAC in formulating strategic research planning and policies regulating research within the KFSH&RC and in allocating research funds according to the scientific merit and relevance of the proposals.

D. The Animal Care & Use Committee (ACUC)

- The ACUC meets on a bi-weekly basis or as required and is charged to evaluate all research proposals and activities involving the use of animals that are undertaken by members of, or within, KFSH&RCS; recommended proposals and activities may be subject to further review and disapproval by the RAC. *An animal is defined as any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes.*
- The ACUC depends on the recommendations of the BRC or CRC regarding the scientific aspects of proposals under its review.
- The ACUC evaluates the proposals according to nationally and internationally accepted standards for issues related to animal care and rights, including the need for animals; the selection of the species; appropriate use of sedatives, analgesics and anesthesia; alternatives to procedures involving pain or distress; methods of housing, euthanasia, and disposition of animals; qualification and training of personnel conducting the research; and medical care of animals.
- The ACUC oversees the KFSH&RC animal programs, procedures, and facilities to ensure that they are consistent with national and international standards.

- The ACUC reviews the animal programs at least once every six months and prepares a report to the Chairman of the RAC.
- The ACUC inspects all of the animal facilities (including satellite facilities, if any) at least once every six months and prepares a report to the Chairman of the RAC.
- The ACUC reviews concerns involving the care and use of animals.
- The ACUC makes recommendation to the RAC Chairman regarding any aspect of the animal programs, facilities, procedures, and personnel training.

E. The Recombinant DNA Committee (RDC)

- The RDC meets on a bi-monthly basis or as required and is charged to evaluate for biosafety issues, all research proposals undertaken by members of, or within, KFSH&RC that involve recombinant DNA molecules. *Recombinant DNA molecules are defined as either: (i) Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or, (ii) Molecules that result from the replication of those described in (i) above.*

*The RDC evaluates the proposals in regard to vectors, organisms in which recombinant DNA will be manipulated and amplified, decontamination and containment levels, and the procedures, practices, and training and expertise of personnel involved; and recommends to the Chairman of the RAC for approval, only those proposals that satisfactorily meet locally and internationally accepted criteria.

- The RDC oversees and assesses, at least annually, all of the KFSH&RC facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research and prepares a report to the Chairman of the RAC.
- The RDC reviews concerns involving the use of recombinant DNA molecules at KFSH&RC.
- The RDC makes recommendations to the RAC Chairman regarding any aspects of the KFSH&RC recombinant DNA research, facilities, or personnel training.
- The RDC adopts emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.

The International Advisory Board (IAB)

The IAB is charged to

- evaluate and give recommendations on issues pertaining to research programs at KFSH&RCHCS
- facilitate KFSH&RC international collaboration in research
- assist in the formation of special site visits for expert evaluation of specific programs at KFSH&RC, and

- 4 evaluate and give recommendations on issues pertaining to RAC Strategic Planning and Policies.

The Office of Research Affairs (ORA)

The Office of Research Affairs (ORA) was established by the Research Centre Administration of KFSH&RC with the following objectives:

- ◆ to coordinate the activities of, and provide support to, the Research Advisory Council (*Proposal Processing Section*)
- ◆ to obtain and administer external research funds for KFSH&RC investigators and to protect the interest of KFSH&RC and its investigators (*Sponsored Research Section*)
- ◆ to protect inventions made at KFSH&RC and to help commercialize research results (*Intellectual Property Section*)
- ◆ to ensure compliance of research activities at KFSH&RC with applicable policies and provide assurance of KFSH&RC compliance to regulatory bodies (*Assurance and Compliance Section*)

- ◆ to provide information to the public on research activities at KFSH&RC and global scientific discoveries (*Scientific Information Section*)

The Annual Research Report Activity, spearheaded by the ORA, is a much awaited yearly research event that is actively participated by multidisciplinary specialties in various medical and clinical affairs and the Research Centre scientific staff. Notable research achievements are presented and publications released in several prestigious high impact journals are given due recognition. From 2005 – 2010, there are 776 publications submitted by both clinical and scientific staff.

As well, the Symposium on the Essentials of Conducting Clinical Research and Workshop on Scientific Writing and Publication Process are held every year to keep abreast with the current trends in research proposal writing and processing.

Currently, there are 115 external grants for ongoing projects (both national and international) awarded to KFSH & RC.

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