RESEARCH ADVISORY COUNCIL

POLICIES
&
GUIDELINES

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POLICY ON RESPONSIBILITY FOR RESEARCH

The increasing complexity and often collaborative nature of modern clinical and biomedical research emphasizes the importance of the chain of personal responsibility for the quality and integrity of the work in which an investigator may be involved. The growth of the King Faisal Specialist Hospital & Research Centre (KFSH&RC) research community and the consequent turnover of the many investigators require that some general policies on research protocol be explicitly stated, rather than be left tacitly to individual discretion or to unstated, but historically expected, behavior patterns.

The goals of science are to produce new knowledge and new unifying concepts. The major ingredients for success in this venture are the well-trained, dedicated, productive and reliable investigators at the laboratory bench or in the clinic, and those having varying degrees of supervisory responsibility. The administration of the KFSH&RC itself must be included in this network.

The progress of science requires the recognition and development of independent investigators. Promising young investigators must be prepared for intellectual and operational independence without the reduction of the responsibility of supervisors, associates, and the KFSH&RC for the quality and integrity of the work. Honest errors and misinterpretations of data are not in question; these must be left for scientific resolution.

It is essential that the interpersonal communications within a research laboratory or clinic permit continual reliable evaluation by collaborating investigators of intellectual standards and expanded knowledge embodied in the content of the on-going research, including, in particular, the original data. While the means for such interchange will vary among laboratories and clinics, it is the responsibility of the senior supervisors to establish and maintain such professional, communicative relationships with their junior colleagues. The ultimate goal should be to promote mutual intellectual and scientific profitability and to encourage independence of thinking and performance.

The scientific documentation and material products of all research carried out at the KFSH&RC are the property of the KFSH&RC. The Department Chairmen have been delegated the responsibility for the scientific non-commercial management of the property. They, in turn, may delegate on-site responsibility to the Unit/Section Head or principal investigator of the particular projects.

In order to avoid misunderstandings, the following guidelines, based on accepted codes of behaviour, are now formally proposed as KFSH&RC policy:

1. The Principal Investigator, his/her immediate supervisor, and all collaborators must

have free access at all times to review all data and products of an investigator's research.

2. All primary data should be promptly recorded in clear, adequate, original and permanent form, which should not leave the laboratory or clinic at any time. These records must be kept for the period outlined in the Policy on Research Records Retention and Access. All such permanent records must remain in the laboratory or unit upon departure of the investigator from the KFSH&RC. Consideration of alternative arrangements for copies to be kept by the KFSH&RC, instead of the original records, must be done with the Department Chairman.

3. Material products – such as cell lines, bacterial clones, other specific organisms and Substances, or software developed and prepared during the course of research – are the property of KFSH&RC and under the jurisdiction of the Principal Investigator. Disposition of material products outside the laboratory/unit is the Department Chairman's responsibility. The individual investigator does not have the right to make any disposition of material products outside the laboratory/unit without authorization of the Department Chairman. Disposition of material products outside the KFSH&RC requires the approval of the KFSH&RC through the Research Advisory Council (RAC) Chairman. The individual investigator and/or Department Chairman do not have the authority to dispose of material products outside the KFSH&RC without RAC approval.

4. When an investigator leaves the KFSH&RC, then the proposed plan for the disposition of the records and material products will receive the approval of the pertinent Department Chairman. If the investigator who is leaving is also the Department Chairman, then the disposition plan will be approved by the Chairman of RAC.

5. The Principal Investigator has the primary responsibility for decisions regarding publications, authorship, and the substance of grant or contract applications. All authors of any publication are expected to share in the responsibility for its scientific content, including its reliability.

6. Free and open discussion of all research activities within the laboratory and clinic should be encouraged. Frequent critical review of on-going projects by all participants as well as informal review by uninvolved colleagues of active work, manuscripts, and projected studies are important in setting the tone for critical self-evaluation. Restrictions on free and open dissemination of the results of KFSH&RC research activities by outside sponsors of research cannot be accepted without the approval of the KFSH&RC through the RAC.

ANIMAL CARE & USE COMMITTEE GUIDELINES &POLICY MANUAL

Proper care, use, and humane treatment of animals used in research, testing, and education require scientific and professional judgment based on knowledge of the needs of the animals and the special requirements of the research, testing and educational programs. The guideline is adapted for the King Faisal Specialist Hospital & Research Centre (KFSH&RC) from the "**Guide**[1]". The information in this document is intended for the administrators of the KFSH&RC, staff of the Laboratory Animal Facility and employees of the Hospital and Research Centre that utilize laboratory animals in their research, teaching and training.

To implement the recommendations adapted from the Guide effectively, an institutional Animal Care and Use Committee (ACUC) was established to oversee and evaluate the program.

Responsibility for directing the program is generally given either to a veterinarian with training or experience in laboratory animal science and medicine or to another qualified professional. At least one veterinarian qualified through experience or training in laboratory animal science and medicine or in the species being used must be associated with the program. The Institution (KFSH&RC) is responsible for maintaining records of the activities of the ACUC and for conducting an occupational health and safety program.

1. Monitoring the Care & Use of Animals

1.1 Institutional Animal Care & Use Committee:

The Chief Executive Director of King Faisal Specialist Hospital & Research Centre (KFSH&RC) is responsible to appoint an ACUC, also referred to as "the Committee," to oversee and evaluate the Institution's animal program, procedures, and facilities to ensure that they are consistent with the recommendations in this policy and procedures manual. It is the responsibility of KFSH&RC to provide suitable orientation, background materials, access to appropriate resources, and, if necessary, specific training to assist ACUC members in understanding and evaluating issues brought before the Committee.

1.2 Committee Membership Should Include the Following:

- A doctor of veterinary medicine, who is certified, or has training or experience in laboratory animal science and medicine or in the use of the species in question.
- At least three practicing scientists experienced in research involving animals.
- At least one technician from the Laboratory Animal Facility.
- At least one member from the Research Centre Management.
- At least three members from the Hospital's Physicians with experience in use of animals in research.
- An unaffiliated member from the Community.

Additional ad hoc members can be added according to anticipated increase in research volume, nature and extent.

[1] "Guide for the Care and Use of Laboratory Animals" Institute of Laboratory Animal Resources, Commission of Life Sciences, National Research Council. National Academy Press, Washington, D.C. 1996

1.3 Terms:
The terms of appointment to the Committee shall be two years.

1.4 Responsibilities:
The Committee is responsible for oversight and evaluation of the animal care and use program and its components described in this policy and procedures manual.

1.5 Functions & Procedures:

- Inspection of facilities.
- Evaluation of programs and animal-activity areas.
- Submission of reports to responsible institutional officials.
- Review of proposed uses of animals in research, testing, or education (ie., protocols).
- Establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the Institution.
- The ACUC must meet as often as necessary to fulfill its responsibilities, but it should meet at least once every four months.
- Records of Committee meetings and of results of deliberations should be maintained.
- The Committee should review the animal-care program and inspect the animal facilities and activity areas at least once every six months. After review and inspection, a written report, signed by a majority of the ACUC, should be made to the responsible administrative officials of the Institution on the status of the animal care and use program and other activities as stated herein and as required by Government Regulations and Policies.

2. Animal Care & Use Protocols

The following topics should be considered in the preparation and review of animal care and use protocols:

- Rational and purpose of the proposed use of animals.
- Justification of the species and number of animals requested. Whenever possible, the number of animals requested should be justified statistically.
- Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation.
- Adequacy of training and experience of personnel in the procedures used.
- Unusual housing and husbandry requirements.
- Appropriate sedation, analgesia, and anesthesia.
- Unnecessary duplication of experiments.
- Conduct of multiple major operative procedures.
- Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated.
- Post procedure care.
- Method of euthanasia or disposition of animal.
- Safety of working environment for personnel.

Occasionally, protocols include procedures that have not previously been encountered or that have the potential to cause pain or distress that cannot be reliably controlled. Such procedures might include:

- Physical restraint
- Multiple major survival surgery
- Food or fluid restriction
- Use of adjuvants
- Use of death as an end point
- Use of noxious stimuli
- Skin or corneal irritancy testing
- Allowance of excessive tumor burden
- Intracardiac or orbital-sinus blood sampling
- The use of abnormal environmental conditions

Relevant objective information regarding the procedures and the purpose of the study should be sought from the literature, veterinarians, investigators, and others knowledgeable about the effects on animals. If little is known regarding s specific procedures, limited pilot studies designed to assess the effects of the procedure on the animals, conducted under ACUC oversight might be appropriate. General guidelines for evaluation of some of those methods are provided in this section, but they might not apply in all instances.

3. Physical Restraint

Physical restraint is the use of manual or mechanical means to limit some or all of the animal's normal movement for the purpose of examination, collection of samples, drug administration, therapy, or experimental manipulation. Animals are retrained for brief periods, usually minutes, in most research applications.

Animals can be physically restrained briefly either manually or with restraint devices. Restraint devices should be suitable in size, design, and operation to minimized discomfort or injury to the animal. Many dogs, non-human primates (eg, Reinhardt 1991, 1995)[2], and other animals can be trained, through use of positive reinforcement, to present limbs or remain immobile for the brief procedures.

Prolonged restraint, including chairing of non-human primates, should be avoided unless it is essential for achieving research objectives and is approved by the ACUC. Less-restrictive systems that do not limit an animal's ability to make normal postural adjustments, such as the tether system for non-human primates and stanchions for farm animals should be used when compatible with protocol objectives. When restraint devices are used, they should be specifically designed to accomplish research goals that are impossible or impractical to accomplish by other means or to prevent injury to animals or personnel.

[2] Reinhardt,V.1991 Training Male Adult Rhesus Monkey To Actively Cooperate During In-Homecage Venipuncture, Anim Technol. 42(1) 11-17. & Reinhardt, V.1995. Restraint Methods Of Laboratory Non-Human Primates: A Critical Review. Animal Welfare, 4:221-238.

The following are important guidelines for restraint:

- Restraint devices are not to be considered normal methods of housing.
- Restraint devices should not be used simply as a convenience in handling or managing animals. The period of restraint should be the minimum required to accomplish the research objectives.
- Animals to be placed in restraint devices should be given training to adapt to the equipment and personnel.
- Provision should be made for observation of the animal at appropriate intervals, as determined by the ACUC.
- Veterinary care should be provided if lesions or illnesses associated with restraint are observed. The presence of lesions, illness, or severe behavioral change often necessitates temporary or permanent removal of the animal from restraint.

4. Multiple Major Surgical Procedures

- Major surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function.
- Multiple major survival surgical procedures on a single animal are discouraged but may be permitted if scientifically justified by the user and approved by the ACUC. For example, multiple major survival surgical procedures can be justified if they are related components of a research project, if they will conserve scarce animal resources, or if they are needed for clinical reasons.
- If multiple major survival surgery is approved, the ACUC should pay particular attention to animal well being through continuing evaluation of outcomes.
- Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures.

5. Food or Fluid Restriction

- When experimental situations require food or fluid restriction, at least minimal quantities of food and fluid should be available to provide for development of young animals and to maintain long-term well-being of all animals.
- Restriction for research purposes should be scientifically justified, and a program should be established to monitor physiologic or behavioral indexes, including criteria (such as weight loss or state of hydration) for temporary or permanent removal of an animal from the experimental protocol.
- Restriction is typically measured as a percentage of the ad libitum or normal daily intake or as percentage change in an animal's body weight.

Precautions that should be used in cases of fluid restriction to avoid acute or chronic dehydration include:

- Daily recording of fluid intake and recording of body weight at least once a week or more often, as might be needed for small animals, such as rodents.

- Special attention should be given to ensure that animals consume a suitably balanced diet because food consumption might decrease with fluid restriction.
- The least restriction that will achieve the scientific objective should be used.
- In the case of conditioned-response research protocols, use of a highly preferred food or fluid as positive reinforcements, instead of restriction, is recommended.

6. Veterinary Care

Adequate veterinary care is provided, included access to all animals for evaluation of their health and well-being. King Faisal Specialist Hospital & Research Centre's mission, programmatic goals, and size of the animal program determine the need for full-time, part-time, or consultative veterinary services.

Ethical, humane, and scientific considerations sometimes require the use of sedatives, analgesics, or anesthetics in animals. An attending veterinarian (ie, a veterinarian who has direct or delegated authority) should give research personnel advice that ensures that humane needs are met and are compatible with scientific requirements. The attending veterinarian shall have the authority to oversee the adequacy of other aspects of animal care and use. These can include animal husbandry and nutrition, sanitation practices, zoonosis control, and hazard containment.

7. Personnel Qualifications and Training

KFSH&RC ensure that people caring for or using animals are qualified to do so. The number and qualifications of personnel required to conduct and support an animal care and use are sufficient to provide adequate quality services.

- Personnel caring for animals are trained appropriately.
- KFSH&RC provides for formal or on-the-job training to facilitate effective implementation of the program and human care and use of animals.
- According to the program scope, personnel will be required with expertise in other disciplines, such as animal husbandry, administration, laboratory animal medicine and pathology, occupational health and safety, behavioral management, genetic management, and various other aspects of research support.
- Employees are encouraged and assisted to partake in non-degree training, with certification programs for laboratory animal technicians and technologists, prepared by the American Association for Laboratory Animal Science (AALAS) [3]and may use commercially available training materials that are appropriate for self-study.
- Personnel using or caring for animals are instructed to participate regularly in continuing education activities relevant to their responsibilities.
- They are encouraged to be involved in local and national meetings of Laboratory Animal Science professional organizations.
- On-the-job training is a part of every technician's job and is supplemented with institution sponsored discussion and training programs and with reference materials applicable to their jobs and the species with which they work.

[3]American Association for Laboratory Animal Science,9190 Crestwyn Hills Drive, Memphis, Tennessee 38125, USA. e-mail: info@aalas.org or http://www.aalas.org

Investigators, technical personnel, trainees, and visiting investigators who perform animal anesthesia, surgery, or other experimental manipulations must be qualified through training or experience to accomplish these tasks in a humane and scientifically acceptable manner.

8. Occupational Health and Safety Personnel

The occupational health and safety program of the King Faisal Specialist Hospital & Research Centre applies to the overall animal care and use program.

- The program is consistent with government regulations and the focus is on maintaining a safe and healthy workplace.
- The program depends on the facility, research activities, hazards, and animal species involved.
- An effective program relies on strong administrative support and interactions among several Institutional functions or activities, including the research program (as represented by the investigator), the animal care and use program (as represented by the veterinarian and the ACUC), the environmental health and safety program, occupational-health services, and administration (eg, human resources, finance, and facility-maintenance personnel).
- Operational and day-to-day responsibility for safety in the workplace, however, resides with the laboratory or facility supervisor (eg, principal investigator, facility director, or veterinarian) and depends on performance of safe work practices by all employees.

9. Hazard Identification and Risk Assessment

King Faisal Specialist Hospital & Research Centre's professional staff who conduct and support research programs that involve hazardous biologic, chemical, or physical agents (including ionizing and non-iodizing radiation) are qualified to assess dangers associated with the programs and to select safeguards appropriate to the risks.

- The occupational health and safety program ensures that the risks associated with the experimental use of animals is reduced to acceptable levels.
- Potential hazards such as animal bites, chemical cleaning agents, allergens, and zoonosis that are inherent in or intrinsic to animal use are also identified and evaluated.
- Health and safety specialist with knowledge in appropriate disciplines are involved in the assessment of risks associated with hazardous activities and in the development of procedures to manage such risks.
- The extent and level of participation of personnel in the occupational health and safety program are based on the hazards posed by the animals and materials used; on the exposure intensity, duration, and frequency, on the susceptibility of the personnel and on the history of occupational illness and injury in the particular workplace.

10. Personnel Training

Personnel at risk are provided with clearly defined procedures for conducting their duties, should understand the hazards involved, and should be proficient in implementing the required safeguards.
Personnel are trained regarding:

- Zoonosis
- Chemical safety
- Microbiologic and physical hazards (including those related to radiation and allergies)
- Unusual conditions or agents that might be part of experimental procedures (including the use of genetically engineered animals and the use of human tissue in immunocompromised animals)
- Handling of waste materials
- Personal hygiene and other considerations (eg, precautions to be taken during personnel pregnancy, illness, or decreased immunocompetence) as appropriate to the risk imposed by their workplace.

11. Personal Hygiene

- It is essential that all personnel maintain a high standard of personal cleanliness.
- Clothing suitable for use in the animal facility and laboratories in which animals are supplied and laundered by the King Faisal Specialist Hospital & Research Centre.
- Appropriate arrangements are made to decontaminate clothing exposed to potential hazards.
- Disposable gloves, masks, head covers, coats, coveralls, and shoe covers are desirable in some circumstance.
- Personnel are instructed to wash their hands and change clothing as often as necessary to maintain personal hygiene.
- Outer garments worn in the animal rooms are not worn outside the animal facility.
- Personnel are not permitted to eat, drink, use tobacco products, or apply cosmetics in animal rooms.

12. Facilities, Procedures and Monitoring

- Facilities required to support occupational health and safety concerns associated with animal care and use programs will vary.
- Because a high standard of personal cleanliness is essential, facilities, and supplies for meeting this obligation should be provided.
- Washing and showering facilities appropriate to the program are available.
- Facilities, equipment, and procedures are designed, selected, and developed to provide for ergonomically sound operations that reduce the potential of physical

injury to personnel (such as might be caused by the lifting of heavy equipment or animals and the use of repetitive movements).
- Safety equipment should be properly maintained and routinely calibrated.

The selection of appropriate animal-housing systems requires professional knowledge and judgment and depends on:

- The nature of the hazards in question
- The types of animals used
- The design of the experiments.

Experimental animals should be housed so that potentially contaminated food and bedding, feces, and urine can be handled in a controlled manner. Facilities, equipment, and procedures are provided for appropriate bedding disposal.

Appropriate methods should be used for assessing exposure to potentially hazardous biologic, chemical, and physical agents where the possibility of exceeding permissible exposure limits (PELs) exists (CFR 1984b)[4].

13. Animal Experimentation Involving Hazards

In selecting specific safeguards for animal experimentation with hazardous agents, careful attention should be given to:

- Procedures for animal care and housing
- Storage and disbursement of the agents
- Dose preparation and administration
- Body-fluid and tissue handling
- Waste and carcass disposal
- Personal protection
- Special safety equipment should be used in combination with appropriate management and safe practices
- As a general rule, safety depends on trained personnel who rigorously follow safe practices.

KFSH&RC should have written policies governing experimentation with hazardous biologic, chemical, and physical agents. An oversight process (such as use of a safety committee) should be developed to involve persons who are knowledgeable in the evaluation of hazards and safety issues. Because the use of animals in such studies requires special considerations, the procedures and facilities to be used should undergo review for specific safety concerns.

Formal safety programs should be established to assess the hazards, determine the safeguards needed for their control, ensure that the staff has the necessary training and skills, and ensure that the facilities are adequate for the safe conduct of the research.

[4] CFR (Code of Federal Regulations) . 1984 b. Title 29 Part 1910, Occupational Safety and Health Standards; Subpart G, Occupational Health and Environmental Control, and Subpart Z, Toxic and Hazardous Substances. Washington, D.C. Office of the Federal Register.

Technical support should be provided to monitor and ensure compliance with Institutional policies.

The Centres for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) publication Biosafety in Microbiological and Biomedical Laboratories (1993)[5] recommend practices and procedures, safety equipment, and facility requirements for working with hazardous biologic agents and materials. Facilities that handle agents of unknown risk should consult with appropriate CDC personnel about hazard control and medical surveillance.

Special facilities and safety equipment are needed to protect the following from exposure to hazardous biologic, chemical and physical agents used in animal experimentation:

- The animal-care and investigative staff
- Other occupants of the facility
- The public
- Animals
- The environment

Facilities used for animal experimentation with hazardous agents should:

- Be separated from other animal housing and support areas, research and clinical laboratories, and patient care facilities.
- Be appropriately identified.
- Have access to them limited to authorized personnel.
- Be designed and constructed to facilitate cleaning and maintenance by mechanical systems.
- Be properly managed and use a double corridor facility or barrier entry system as an effective means of reducing cross contamination.
- Have floor drains that always contain liquid or be sealed effectively by other means.
- Have automatic trap priming to ensure that traps remain filled.

Hazardous agents should be contained within the environment.

- Control of airflow (such as through the use of biologic-safety cabinets) that minimizes the escape of contaminants is a primary barrier sued in the handling and administration of hazardous agents and the performance of necropsies on contaminated animals (CDC 1995)[6].
- Special features of the facility such as airlocks, negative air pressure, air filters, and redundant mechanical equipment with automatic switching and secondary barriers should be aimed at preventing accidental release of hazards outside the facility and work environment.

[5] CDC (Centres for Disease Control and Prevention and NIH (National Institute of Health). 1993 Biosafety in Microbiological and Biomedical Laboratories. 3rd ed. HHS Publication No. (CDC) 93-8395. Washington, D.C.: U.s. Government Printing Office.
[6] CDC (Centres for Disease Control and Prevention and NIH (National Institute of Health). 1995 Primary Containment of Biohazards: Selection, Installation and Use of Biological Safety Cabinets. Washington, D.C.: U.S. Government Printing Office.

Exposure to anesthetic waste gases should be limited. This is usually accomplished by using various scavenging techniques. If ether is used, personnel safety should be ensured by proper use of signs and by using equipment and practices to minimize risks associated with its explosiveness.

14. Personal Protection

- Personal protective equipment should be provided, and other safety measures should be adopted when needed.
- Animal-care personnel should wear appropriate institution-issued protective clothing, shoes or shoe covers, and gloves.
- Clean protective clothing should be provided as often as necessary.
- If it is appropriate, personnel should shower when they leave the animal-care, procedure, or dose-preparation areas. Protective clothing and equipment should not be worn beyond the boundary of the hazardous-agent work area or the animal facility.
- Personnel with potential exposure to hazardous agents should be provided with personal protective equipment appropriate to the agents (CFR 1984c) [7]. For example, personnel exposed to non-human primates should be provided with such protective items as gloves, arm protectors, masks, and face shields.
- Hearing protection should be provided in high-noise areas.
- Personnel working in areas where they might be exposed to contaminated airborne particulate material or vapors should be provided with suitable respiratory protection.

15. Medical Evaluation and Preventive Medicine for Personnel

Development and implementation of a program of medical evaluation and preventive medicine should involve input from trained health professionals, such as occupational-health physicians and nurses. Confidentiality and other medical and legal factors must be considered in the context of appropriate federal, state, and local regulations.

- A health history evaluation before work assignment is advisable to assess potential risks for individual employees.
- Periodic medical evaluations are advisable for people in some risk categories. An appropriate immunization schedule should be adopted.
- It is important to immunize animal-care personnel against tetanus. In addition, pre-exposure immunization should be offered to people at risk of infection or exposure to such agents as rabies or hepatitis B virus.
- Vaccination is recommended if research is to be conducted on infectious diseases for which effective vaccines are available.
- Specific recommendations can be found in the CDC and NIH publication Biosafety in Microbiological and Biomedical Laboratories (1993)[8].
- Pre-employment or pre-exposure serum collection is advisable only in specific

[7] CFR (Code of Federal Regulations) . 1984 C. Title 29 Part 1910, Occupational Safety and Health Standards; Subpart I, Personal Protective Equipment. Washington, D.C. Office of the Federal Register.

[8] CDC (Centres for Disease Control and Prevention and NIH (National Institute of Health). 1993 Biosafety in Microbiological and Biomedical Laboratories. 3rd ed. HHS Publication No. (CDC) 93-8395. Washington, D.C.: U.S. Government Printing Office

circumstances as determined by an occupational health and safety professional. In such cases, identification, traceability, retention, and storage conditions of samples should be considered, and the purpose for which the serum samples will be used must be consistent with applicable government laws and regulations.

16. Zoonosis

Zoonosis surveillance should be a part of an occupational health. Personnel should be instructed to notify their supervisors of potential or known exposures and of suspected health hazards and illnesses. Clear procedures should be established for reporting all accidents, bites, scratches, and allergic reactions.

Non-human primate diseases that are transmissible to humans can be serious hazards.

- Animal technicians, clinicians, investigators, predoctoral and postdoctoral trainees, research technicians, consultants, maintenance workers, security personnel, and others who have contact with non-human primates or have duties in non-human-primate housing areas should be routinely screened for tuberculosis.
- Because of the potential for Cercopithecine herpesvirus I (formerly Herpesvirus simiae) exposure personnel who work with macaques should have access to and be instructed in the use of bite and scratch emergency-care stations (Holmes and others 1995)[9].
- King Faisal Specialist Hospital & Research Centre has an established procedure for ensuring medical care for bites and scratches.

[9] Holmes, G.P. et al and the B-Virus Working Group. 1995. Guidelines for Prevention and Treatment of B-virus Infections In Exposed Persons, Clin.Infect. Dis. 20:421-439

POLICY ON INTEGRITY IN THE PERFORMANCE OF RESEARCH

1. Preamble

In any human endeavor, including scientific research, there are individuals who, for various reasons, do not adhere to appropriate norms of behavior. Historically, the major mechanism for the detection and control of misconduct in scientific research has been the system of fundamental checks and balances which is built into the nature of scientific inquiry, bolstered by such activities as peer review, publication, and confirmation. However, several recently publicized cases have demonstrated that this system is sometimes insufficient. In the present climate, it has become necessary for scientific research institutions to establish formal mechanisms and procedures to deal with allegations of misconduct in research. Such formal procedures are essential to assure the protection of the rights of (1) the accused, (2) innocent associates, (3) those making the allegations, (4) the institution, and (5) any outside funding source, until the basis of the allegations can be examined and a resolution of the problem can be determined.

Therefore, the King Faisal Specialist Hospital & Research Centre (KFSH&RC) has established this "Policy on Integrity in the Performance of Research." This Policy is intended to apply to the KFSH&RC and to the Affiliated Hospitals.

2. General Principles

For the purposes of this policy, "research" means any systematic investigation (i.e., the gathering and analysis of information) designed, in whole or in part, to develop or contribute to generizable knowledge; "human subject" means an individual about whom an investigator obtains (i) data through intervention or interaction with the individual or (ii) identifiable private information (e.g., medical records); "an animal" means any live, vertebrate animal used or intended for use in research, research training, experimentation, or biological testing or for related purposes"; and "misconduct" means fabrication, falsification, plagiarism, involving human subjects or animals in research without prior approval of the Research Advisory Council (RAC), or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. "Misconduct" does not include honest error or honest difference in interpretations or judgments of data.

When the possibility of misconduct in research is raised, the RAC shall conduct an initial inquiry and, where appropriate, a formal investigation, as set forth below. The RAC shall conduct inquiries and investigations so as to:

- protect, to the maximum extent possible, the privacy of an individual who in good faith reports apparent misconduct (a "reporter") as well as the confidentiality of the information;
- provide the individual alleged to have engaged in misconduct (the "respondent") with (i) confidential treatment to the maximum extent possible, (ii) a prompt, thorough and

impartial inquiry and, where appropriate, investigation, and (iii) an opportunity to comment on allegations and findings of the inquiry and/or investigation;
- secure necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence, and
- protect against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

The RAC shall, after consultation with the Council & Supervisor of Executive Management (C&SEM), or his or her designee, have the authority to seek the services of appropriate consultants and experts. The RAC shall also have the authority, prior to concluding any inquiry or investigation, to take such actions as they deem necessary to protect the interests of the research subjects and of the sponsors of research, and to present or correct the dissemination of the results of research in which misconduct may have been involved.

If the respondent has (or had at the time of the alleged misconduct) an appointment with another institution, the RAC shall conduct inquiries and, if appropriate, investigations in consultation with, and with the assistance of, the Executive Director of that institution.

If the alleged misconduct pertains to research or related activities funded in whole or in part by an external agency, the procedures set forth in the agreement with the agency, if any, shall apply in addition to the procedures set forth herein.

Nothing in these Procedures shall preclude or delay the Chairman or Head of the Service, Department, or Unit, or any other appropriate supervisor of the respondent, from conducting an independent review and taking corrective action as necessary or appropriate whenever a Professional Staff member or employee engages in conduct that is, or may be, detrimental to the quality of patient care or disruptive to the institution's operations.

3.General Responsibility Over Allegations of Misconduct

The RAC Chairman shall ensure that the C&SEM as well as the Executive Director and the Chairman or Head of the Service, Department, or Unit of the respondent, and any other appropriate supervisor of the respondent, are, and remain, informed of the matter. The RAC Chairman shall also be responsible for coordinating the inquiry and any investigation into the allegation.

4.The Initial Report and Preliminary Assessment

Any Professional Staff member or employee of the KFSH&RC, or any of its Affiliated Hospitals subject to this Policy, who learns, from any source, of an allegation or possible instance of misconduct in research shall immediately notify the Chairman of the RAC. Research subjects or their representatives should also notify the Chairman of the RAC, directly or via the Assurance & Compliance Section of the Office of Research Affairs, of any complaints, against the investigator(s).

The Chairman of the RAC may conduct a preliminary assessment of the allegation. If on the basis of this preliminary assessment the RAC Chairman determines that the allegation is not sufficiently supported to warrant a further inquiry, he or she may submit a written summary of

the basis for this determination to the C&SEM, along with a recommendation that no further action be taken. The C&SEM may, on the basis of such a summary and recommendation, instruct that the matter be closed.

If the matter is not closed after a preliminary assessment, the RAC Chairman shall notify the RAC of the matter. The RAC Chairman, in consultation with the members of the RAC, will appoint an Ad Hoc Committee to conduct an initial fact-finding inquiry into the matter. The Ad Hoc Committee may, depending on the circumstances, include members from outside the KFSH&RC and its Affiliated Hospitals. The RAC Chairman will also notify the respondent and any scientific research collaborator in writing of the membership and charge to the Ad Hoc Committee.

5.The Initial Inquiry by the Ad Hoc Committee

Except for matters closed after a preliminary assessment, as described above, the Ad Hoc Committee shall be responsible for conducting the initial fact-finding inquiry into possible misconduct in research. The Ad Hoc Committee shall determine whether the respondent has engaged in misconduct in research, or, if the Ad Hoc Committee is unable to make such a determination, whether an allegation or apparent instance of misconduct warrants a further, formal investigation.

In performing its inquiry, the Ad Hoc Committee may review such documents and conduct such interviews, as it deems necessary and appropriate. The Ad Hoc Committee may delegate authority to its members, and in making its determination, may rely upon reports and recommendations of such members and of consultants and experts retained by the Ad Hoc Committee. The Ad Hoc Committee may ask the appropriate Executive Director to perform a special audit of the fiscal activities of the relevant or related research. The Ad Hoc Committee may take any action without a meeting if notice of the proposed action is given to all members, and no member objects.

The Ad Hoc Committee shall prepare a written report that states what evidence was reviewed, summarizes relevant interviews, and states the conclusions of the inquiry. The Ad Hoc Committee shall give a draft of the report to the respondent and, if appropriate, to any collaborator or supervisor associated with the research in which misconduct has been alleged. If any of them comment on the draft report, the comment shall be made part of the final report.

If the Committee concludes that the respondent engaged in misconduct, the report may include recommendations to the RAC Chairman for appropriate actions and sanctions. These may include:

- the withdrawal of all pending involved abstracts and papers;
- notification of editors of journals in which involved research was reported;
- notification of all institutions with which the respondent had been previously affiliated and where there is reason to believe the validity of previous research might be questionable; and
- if the respondent individual is a member of the Professional Staff of an Affiliated Hospital, appropriate corrective action under the applicable Professional Staff Bylaws.

The Ad Hoc Committee shall submit the report to the RAC Chairman, who shall provide copies to appropriate people in the KFSH&RC or Affiliated Hospitals.

6. Formal Investigation and Other Further Action by the RAC

The RAC shall review the report of the Ad Hoc Committee.

If the Ad Hoc Committee, based on its initial fact-finding inquiry, is unable to determine whether the respondent has engaged in misconduct in scientific research and concludes that a further formal investigation is warranted in order to make that determination, the RAC shall conduct such an investigation. In performing such investigation, the RAC shall have all the powers and authority possessed by, and shall review evidence and prepare its report in the same manner as applicable to, the Ad Hoc Committee in conducting the initial inquiry, and may request the assistance of, and rely upon, members of the Ad Hoc Committee. If the RAC Committee concludes that the respondent engaged in misconduct, the report shall include recommendations for appropriate actions and sanctions.

If the Ad Hoc Committee concludes that a formal investigation is not warranted, the RAC may accept the Ad Hoc Committee's report with or without comments or modifications. Alternatively, the RAC may on its own initiative undertake a further investigation in accordance with the previous paragraph.

The RAC shall give a copy of its final report, or of the Ad Hoc Committee's report as accepted by the RAC, to each member of the RAC and to the respondent. The RAC Chairman shall provide copies to appropriate people in the KFSH&RC and Affiliated Hospitals.

7. Subsequent Action of the C&SEM

If the RAC's final report, or the Ad Hoc Committee's report as accepted by the RAC, concludes that the respondent did not engage in misconduct, the C&SEM shall take appropriate actions to restore the reputation of the respondent, and also to protect the position and reputation of the reporter.

If the RAC's final report, or the Ad Hoc Committee's report as accepted by the RAC, concludes that the respondent did engage in misconduct, the C&SEM shall see that all appropriate actions are carried out, that the respondent is informed in writing of the actions that are to be taken, and that any outside funding sources are informed of the results of the inquiry and/or investigation and the actions which will be taken.

The RAC will also review the practices, policies and procedures of the KFSH&RC and Affiliated Hospitals for (1) promoting proper conduct of research, and (2) investigating allegations of misconduct, and in the light of the experience gained from the matter just completed, and shall make recommendations for modifications as it deems necessary or desirable.

POLICY ON RESEARCH RECORDS RETENTION AND ACCESS

The preparation and retention of appropriate records is an essential component of a research endeavor. The KFSH&RC, its members and its trainees have a common interest and a shared responsibility to assure that research is appropriately recorded, archived for a reasonable length of time, and available for review under appropriate circumstances. Original research records are essential to protect intellectual property rights, to answer ongoing questions regarding management of a research program, and to address possible questions that may arise regarding the propriety of research conduct.

1. Definition of Research Records

Research records include (but are not limited to) material contained in research notes, laboratory notebooks, case report forms, data collection forms, and in other media such as computer and compact disks, videotapes and machine printouts. Research materials or products generated by the research may also become archived research records. Consent Forms are an essential part of the record of research involving human subjects.

2. Retention of Research Records

The principal investigator has the obligation to insure that, for all aspects of his/her research program, sufficient records are kept to document the experimental methods and accuracy of data collection as well as the methods and accuracy of data interpretation. The principal investigator has an obligation to discuss the responsibilities of data management and retention with other members of his/her research team. This policy does not create an obligation to retain the research records of an **unfunded** project unless it results in publication or involves the use of animals or human subjects.

Research records should be archived for a minimum of five years after final reporting or publication of a project. The records archived should be the originals whenever possible. In addition, the records should be kept for as long as may be required to protect any patents resulting from this work or required by an external funding source. If any questions regarding the research are raised during the five-year retention period, the records should be kept until such questions are fully resolved. In the event a principal investigator leaves the KFSH&RC for any reason, he/she must notify the Research Advisory Council and his/her supervisor of the designated custodian and location of research records covered by this policy.

3. Access to Research Records

The Research Advisory Council has the right of access to the supporting records for all research at the KFSH&RC or supported by KFSH&RC-sponsored funds provided such access to the records shall be for reasonable cause, at reasonable times and after reasonable notice. The KFSH&RC's right of access to the data shall continue regardless of the location of the

responsible investigator. Extramural sponsors providing support for research at KFSH&RC may also have the right to review the data and records resulting from that extramural support. Co-investigators and trainees who are an integral part of a research project have the right to review all records and data that are part of those projects.

INTELLECTUAL PROPERTY POLICY

1. PREAMBLE

KFSH&RC recognizes that patentable inventions may be made in the course of research or other activities sponsored by KFSH&RC and/or by others through KFSH&RC. It is the policy of KFSH&RC to maximize the benefits to the individual who makes such patentable inventions, to KFSH&RC and to the general public; and to stimulate initiative in the staff, employees, trainees, and students of KFSH&RC. KFSH&RC recognizes that this may best be accomplished through patenting and licensing such inventions in a manner consistent with the public interest, and for such purpose KFSH&RC hereby establishes the intellectual property policy set forth herein.

2. POLICY

A. In order to protect the public good and KFSH&RC, and in order to fulfill obligations to research sponsors, KFSH&RC shall claim equity in all discoveries and its right to acquire the title and control to such discoveries where the discoveries are made by staff, employees, trainees, or students working on or arising from programs supported in whole or in part by funds, space, personnel, or facilities provided by KFSH&RC.

B. When a discovery is made by an inventor outside of any program conducted by KFSH&RC, and the inventor can demonstrate that KFSH&RC did not provide or administer significant funds, space, personnel, or facilities for work leading to the discovery, the discovery shall remain the exclusive property of the inventor or his/her sponsor. KFSH&RC shall not ordinarily consider provision of office, classroom, or library facilities as constituting significant use of KFSH&RC funds, space, personnel or facilities. For the purposes of this policy, the term “Inventor” shall include all individuals who participated in or signed a disclosure statement reporting a discovery or invention.

C. When necessary, the Research Advisory Council (RAC) of the KFSH&RC shall decide whether an invention or discovery shall be classified under paragraph A or paragraph B of this section.

3. INTELLECTUAL PROPERTY PROCEEDS

A. Where KFSH&RC is entitled to equity in a discovery and after patent prosecution and any other costs are recovered, each inventor will be given:
- a share of the first $2,000.00 of royalties or other payments received on a licensed invention for each year the agreement is in effect, provided sufficient royalties are received;
- a share of fifteen percent (15%) of the license royalties received between$2,000 and $50,000; and
- a share of 25% of license royalties in excess of the first $50,000 received.

B. The sum of these, as appropriate, will be the inventor's share in royalties or other payments received by the KFSH&RC.

C. The remainder of the royalties or other payments received will be distributed as follows: two thirds to the unit(s)/section(s) in which the invention was made and one third to the KFSH&RC General Research Fund.

D. Royalty payments are distributed in January and July of each year. The royalties are received and distributed by the RAC on behalf of KFSH&RC. No royalties are ever paid directly to any inventor by any license. A formal review and approval process is followed in receiving and administering royalty distributions.

E. In the event an inventor ceases to be associated with the KFSH&RC, he or she shall continue to receive the inventor's share.

4. DISCLOSURES

Because the securing of rights in discoveries and inventions depends on prompt and efficient patent application and administration, all staff, employees, trainees, and students of KFSH&RC who make inventions or discoveries shall immediately disclose said inventions or discoveries to the Office of Research Affairs (ORA). This disclosure obligation shall apply to all inventions and discoveries whether they fall under Paragraph A or B under the Policy section.

5. PATENT ADMINISTRATION

Within 60 days following disclosure by the Inventor of his or her invention to the ORA, the ORA shall inform the Inventor in writing of the decision of the Research Advisory Council (RAC) on whether rights of ownership to the invention will be retained by the KFSH&RC or released to the Inventor and in regard to which countries. Such a decision shall be recommended by an ad hoc committee appointed by the Chairman of the RAC and approved by the RAC Chairman. The inventor shall disclose to the RAC and the ad hoc committee any and all details about his/her invention that are required to make such a decision.

The inventor shall then complete the patent application(s) and file it with the ORA in a reasonable time. The ORA shall have the patent reviewed and filed by a patent lawyer in the applicable country/countries within 3 months from receiving a completed patent application. If the ORA fails to inform the inventor of the RAC decision as to the rights of ownership of the invention or to file the patent application in the applicable country/countries, in the allocated time, the RAC Chairman shall, in consultation with the Inventor, determine what other disposition, if any, shall be made of the invention and its development.

6. DISPUTE REVIEW

Any disputes that arise under this policy shall be referred to the RAC, who, after consultation with the ORA, shall recommend action to the RAC Chairman. If the inventor is not satisfied with the RAC decision, he/she shall have the right to submit his/her claim to the committee established for resolving such issues in the King Abdulaziz City for Science and Technology (KACST) in accordance with the Saudi patent law. The decision of the KACST committee is appealable to the Board of Grievance whose decision shall be final.

7. CONSULTING AND OTHER AGREEMENTS

The rights of KFSH&RC under this policy, and the interest of sponsors under research grants or contracts, may not be abrogated or limited by consulting agreements or other contracts entered into between KFSH&RC staff, employees, trainees and students and an outside organizations or employers. KFSH&RC staff, employees, trainees, and students should inform outside employers of their obligations, and commitments to the KFSH&RC under this policy. Such staff, employees, trainees, and students shall ascertain that patent clauses in their agreements are not in conflict with their obligations to the KFSH&RC or this policy or the laws and regulations of the Kingdom of Saudi Arabia. Each member of the staff, employees, trainees and students should make his/her obligations to the KFSH&RC clear to those with whom such agreements may be made, and should ensure that they are provided with a current statement of the KFSH&RC policy. Upon request, the ORA will provide a standard clause which may be inserted in the agreement. This clause will put third parties on notice as to the KFSH&RC rights under this policy with respect to inventions and discoveries. In case of conflict of interest, the KFSH&RC reserves the ultimate right to determine the final disposition of the rights and interests involved.

Rights and obligations under this agreement shall survive any termination of enrollment or employment at KFSH&RC.

Nothing herein contained is intended to grant or dispose of any right, title, and interest to any disclosure, idea, improvement, or invention, whether patentable or not, which has been supported or funded by outside parties who acquire rights to such disclosure, idea, improvement and invention.

8. APPLICABLE LAWS

This policy is subject to the laws of Saudi Arabia including the patent law issued per Royal Order # M/38 dated 10.6.1409, (17 Jan 1989) and any amendments thereof. The Board of Grievance shall have the final jurisdiction for any dispute.

POLICY ON RESEARCH CONFLICTS OF INTEREST & COMMITMENT

1. Definitions

For purposes of this Policy, the following definitions apply:

A. "Concern": any corporation, association, trust, partnership, firm, venture, or other entity other than the KFSH&RC.
B. "Equity": ownership of stock or stock options or a contractual or other right to acquire stock or options or interests as an owner, proprietor, partner or beneficiary, including interests held through trusts or personal holding companies.
C. "Family": an Investigator's spouse, children, parents and siblings.
D. "Investigator": the principal investigator, co-investigators, and any other person at KFSH&RC who is responsible for the design, conduct, or reporting of research or educational activities. In this context, the term Investigator includes the "Investigator's" Family.

2. Introduction

The primary goal in the conduct of biomedical research at the King Faisal Specialist Hospital & Research Centre (KFSH&RC) is the advancement of basic and applied medical science. The KFSH&RC is also committed to the training of scientists and clinicians and the propagation of the fruits of research activities. However, research endeavors must never compromise the institution's overriding mission to deliver patient care in the most appropriate, objective, and effective manner. The academic medical culture in which Investigators and clinicians simultaneously pursue these research, education, and patient care goals must strike a carefully crafted balance among these objectives. To the extent that industrially-sponsored research, clinical trials, technology licenses, and other relationships with industry can be accomplished without upsetting this delicate balance, they should be encouraged. To the extent they inhibit the pursuit of these goals, they should be avoided.

The intensified interest of the private sector in acquiring rights to commercialize the intellectual and tangible research property arising from biomedical research activities has placed new pressures on the special culture of this and other academic medical centers. While this commercial activity may increase the opportunities for creation of beneficial products, it will also increase the potential for conflicts of interest for Investigators.

The potential for conflict may arise in the form of offers of Equity, consulting opportunities, or other financial interests in outside commercial ventures relating to or deriving from an Investigator's research activities. A substantial involvement in the scientific or management activities of an outside company, through either consulting or operating responsibilities, carries with it the additional potential of conflict of commitment.

This Research Conflicts Policy establishes a procedure for careful scrutiny of commercial opportunities offered to Investigators. In doing so, the policy intends to guide the conduct of Investigators in order to minimize the likelihood of conflict with the Investigator's primary obligations to the KFSH&RC, while at the same time allowing the development of beneficial commercial relationships. In addition to guiding the activities of individuals engaged in basic research, it is equally important that this policy provide guidance to clinical investigators and to those responsible for training and guiding the activities of other Investigators. Particular scrutiny will be applied to the commercial relationships of Investigators with significant management or supervisory responsibilities, inasmuch as these relationships have the potential to create undue influence (or the appearance of undue influence) within a department, service, or the KFSH&RC**.**

3. Disclosure Requirements

This Research Conflicts Policy is predicated on the belief that disclosure of potential conflicts of interest and commitment will effectively address the vast majority of situations and that ameliorative measures can be taken in most others. It is anticipated that few conflicts will require formal resolution under this policy (see Attachment A). For these reasons, the Research Conflicts Policy requires the disclosure and review of Investigators' relationships with commercial Concerns and establishes a mechanism to limit the extent of such involvement in specific situations.

At the time of recontracting and/or of submitting a research proposal, each Investigator must complete and submit a Financial Interest Disclosure Statement (see Attachment B) by which the Investigator will disclose those Concerns that support his or her research and other academic activities and those Concerns with which he or she has a consulting agreement. Each Investigator should also disclose on a case-by-case basis potential or actual conflicts of interest or commitment between the Investigator's research activities and his or her outside interests. Finally, each Investigator is required to disclose in advance any proposed acquisition of Equity by the individual, by a member of the individual's Family, or by a Concern in which he or she has an Equity interest, in a Concern whose business is related to the Investigator's area of research or to research that the Investigator directs or controls.
All such ad hoc disclosures are to be made in writing to the Chairman of the Research Advisory Council (RAC). The disclosure must include the details of the proposed or existing equity position, research activities and sponsorship, or licensing arrangements.

All disclosed information will be treated confidentially, subject to review only as necessary to implement this Policy.

4. Resolution

The RAC Chairman will review each disclosure. Apparent conflicts will be referred to the RAC which will determine whether the proposed action will result in a significant conflict or appearance of conflict and, if so, whether any measures can be implemented to ameliorate the conflict. Such measures may include 1) requiring that public disclosure of the identified interest

be made, 2) requiring that the data and research results be reviewed by independent reviewers identified by the RAC and the Investigator, 3) requiring that the research plan be modified, 4) requiring that the Investigator be disqualified from a portion of the research, 5) requiring that the Investigator divest certain significant financial interests, and 6) requiring that the Investigator sever relationships that create the conflicts. The resolution plan will be developed into a Memorandum of Understanding with the collaboration of the Investigator. Alternatively, the RAC may determine that a proposed activity is sufficiently free of conflict to allow it to proceed, or that a proposed activity is sufficiently inappropriate to prohibit it.

In resolving unacceptable conflicts of interest, the Investigator's primary loyalty and commitment to the KFSH&RC should favor the preservation of the KFSH&RC's research endeavors and funding sources over the Investigator's personal financial reward. Accordingly, the KFSH&RC prefers that these unacceptable conflicts be resolved by the investigator declining a proposed acquisition of equity or other industrial relationship, or by divesting existing holdings or terminating existing relationships. In contrast, because an investigator's election instead to decline a particular industrial source of research funding or a particular research role would tend to discourage potentially productive research arrangements, the KFSH&RC does not consider such an election desirable. Rather than having the Investigator decline funding, this policy encourages the establishment of ameliorative measures so that, where possible, the Investigator's outside activities and research interests can comfortably coexist.

5. Appeal of a Resolution Plan

Investigators may appeal a resolution to the Counselor and Supervisor of Executive Management (Chief Executive Director) whose decision will be final.

Attachment A

The following commentary and examples are intended to provide guidance in the identification of conflicts of interest or commitment. The list does not cover all possible situations that might involve an actual or apparent conflict of interest. It is intended to be illustrative only.

1. General Considerations

Investigators involved in business ventures as owner, operator, or major investor must be alert to the possibility that a conflict may arise. If the enterprise does no business with the KFSH&RC, only the area of conflict of commitment is likely to be involved.

If the enterprise does business with the KFSH&RC, or might do business with the KFSH&RC, the Investigator is expected to disclose that fact. Generally, there will be no conflict if the Investigator is not in a position to influence the KFSH&RC with respect to the business of the enterprise in which the member holds an interest.

An Investigator may not review, approve, or administratively control contracts when the contract is between the KFSH&RC and a company in which the Investigator has a substantial financial interest or when the contract is with a member of the Investigator's Family or when a member of the Investigator's Family is an employee of the contractor and directly involved with activities included under the contract or has a substantial interest in the contractor.

No gifts or accommodations of any nature may be accepted by the Investigators when to do so could possibly place them in a prejudicial or embarrassing position, interfere in any way with the impartial discharge of their duties to the KFSH&RC or reflect adversely on their integrity or that of KFSH&RC.

2. Permissible Activities

The following activities are clearly permissible and does not require disclosure as an actual or potential conflict under the terms of this policy:

Example 1.
Acceptance of salary, royalties, or other remuneration from KFSH&RC.

Example 2.
Acceptance of income from seminars, lectures, or teaching engagements sponsored by public or non profit entities.

Example 3.
Income from service on advisory committees or review panels for public or non profit entities.

The following activities are clearly permissible but should be disclosed for information:

Example 1.
Acceptance of royalties under the terms of the KFSH&RC's Patent Policy or publication royalties or honoraria for commissioned papers, lectures, manuscripts, or research proposal reviews.

Example 2.
Services to outside educational, professional, scientific, cultural, civic, business or other organizations that enhance the value of the Investigator to the KFSH&RC and do not adversely affect the Investigator's primary commitment to the KFSH&RC.

3. Apparent Conflicts Requiring Prior Disclosure and Resolution

The following activities have the potential to create conflicts of interest or commitment and should be disclosed (and the conflicts resolved) prior to being undertaken.

Example 1.
An Investigator may not directly or indirectly lease, rent, trade, or sell real or personal property to the KFSH&RC without full disclosure of the relevant facts.

Example 2.
An investigator may not possess a substantial interest in or participate in the profits of any organization that deals or seeks to deal with the KFSH&RC without full disclosure of the relevant facts. Participation through stockholdings, mutual funds and similar vehicles is not a conflict unless the stocks of the organization held by the Investigator constitute a substantial holding as determined by the RAC.

Example 3.
An investigator may not accept appointment as an officer or director or serve in any management capacity in external commercial, industrial, business or financial organization of profit-making enterprise that deals or seeks to deal with the KFSH&RC without full disclosure of the relevant facts.

4. Possible Conflicts

Conflict is possible, even if unlikely, in situations such as those listed in the following examples, and Investigators should give careful consideration to that potential. In many cases the potential for conflict can be removed by disclosure.

Example 1.
Relationships that might enable members to influence KFSH&RC's interactions with outside organizations in ways that may lead to personal gain, to the taking of improper advantage by anyone, or the improper diversion of KFSH&RC assets from the primary missions of the KFSH&RC, including the time and talents of its faculty and staff. Such relationships include providing accommodations and travel expenses to an Investigator by a commercial entity such as

a pharmaceutical company sponsoring "marketing research" and introducing drugs to the KFSH&RC formulary.

Example 2.
Situations in which an Investigator, while serving as a consultant to an external organization has access to unpublished, privileged information from a colleague that has potential commercial value and wishes to provide that information to the external organization.

Example 3.
Situations where an Investigator directs students (including Residents and Fellows) into a research area or other activity from which the member intends to realize personal financial gain. A conflict may arise if students are directed to areas of lesser scientific or scholarly merit to enhance the potential for monetary gain or if the financial potential exists only for the investigator.

Example 4.
Situations where the investigator is asked to assume executive or managerial positions with outside organizations that might seriously divert the investigator's attention from KFSH&RC duties, or create other conflicts of loyalty.

Example 5.
Disclosure or use for personal profit of unpublished information coming from KFSH&RC research or other confidential KFSH&RC sources, or assisting outside organizations by giving them access to such information except as may be authorized by official KFSH&RC policies.

Example 6.
Consultation that impose obligations that conflict with KFSH&RC's Intellectual Property Policy or with KFSH&RC's obligations to research sponsors.

Example 7.
Situations where a substantial body of research that could and ordinarily would be conducted by the Investigator within the KFSH&RC is directed elsewhere.

Example 8.
Situations where the Investigator is invited to advise or serve an organization doing business in the general area of the Investigator's KFSH&RC responsibility or which is related to that field.

Example 9.
Situations where an investigator is offered a position on a scientific or administrative board of an organization that has research contracts with the investigator's unit/section.

Example 10.
Situations where an investigator is offered research support from an organization in which an Investigator serves as a director, an investigator of an advisory board, or as a consultant, or in which the Investigator holds a significant equity position.

Example 11.
Situations where the investigator occupies a position in an enterprise doing business in the area of the Investigator' KFSH&RC responsibility or which is related to that field.

Example 12.
Situations where the investigator is involved in independent business ventures as owner, operator, or major investor, particularly if the corporation is doing business with the KFSH&RC.

Example 13.
Situations in which an investigator can require others to purchase a product in which the Investigator has a proprietary interest and from which the Investigator will receive income.

5. Conflicts of Commitment

Assessment of a conflict of commitment is more difficult than assessment of a conflict of interest. Generally, such conflicts will be apparent in the failure of Investigators to discharge fully the role and duties expected of them.

1. Commitments that involve frequent or prolonged absence from KFSH&RC on non-KFSH&RC business.
2. Commitments that engage a substantial portion of the time an investigator is expected to spend in KFSH&RC related activities and which thereby dilutes the amount or quality of participation in the instructional, scholarly, or administrative work of the KFSH&RC.

ATTACHMENT B

Investigator Financial Interest Disclosure

Who is covered?

"Investigator" means the principal investigator, co-investigators, and any other person at KFSH&RC who is responsible for the design, conduct, or reporting of research or educational activities. In this context, the term Investigator includes the "Investigator's" Family.

What must be disclosed?

Each Investigator shall disclose all financial interests:

(i) that would reasonably appear to be directly affected by his/her research or educational activities.
(ii) in entities whose financial interests would reasonably appear to be directly affected by such activities.

What is covered?

"Financial interests" means anything of monetary value, including, but not limited to, salary, accommodations, travel expenses, or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The term does not include:

(1) Salary, royalties, or other remuneration from KFSH&RC;
(2) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
(3) Income from service on advisory committees or review panels for public or non-profit entities;

Investigator Financial Interest Disclosure

Name: _____

ID Number: _____ Department: _____

I am disclosing the following financial interests and attaching supporting documentation (in an envelope marked confidential) that identifies the business enterprise or entity involved and the nature and amount of the interest:
("financial interests" are defined on page 1.)

_____ Salary or other payment for services (e.g., consulting fees or honoraria).
_____ Equity interests (e.g., stocks, stock options, or other ownership interests).
_____ Intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
_____ Other financial interest that possibly could affect or be perceived to affect the results of my research or educational activities.

I have no financial interests to disclose: _____
Initials

Further I agree:

- To update this disclosure either on an annual basis, or as new reportable financial interests are obtained.
- To cooperate with the Research Advisory Council (RAC) in the development of a Memorandum of Understanding (MOU) that constitutes a conflict of interest resolution plan.
- To comply with any conditions or restrictions imposed by the RAC to manage, reduce, or eliminate actual or potential conflicts of interest.

Signed: _____ _____
(Original signature only – a "per" signature is not acceptable) Date

Endorsements:

I have reviewed the financial interest disclosure and believe that an MOU is
☐ required ☐ not required

Department Chairman: _____ _____
Signed Date

I have reviewed the financial interest disclosure and believe that an MOU is
☐ required ☐ not required

RAC Chairman _____ _____
Signed Date

POLICY ON CONSULTING AGREEMENTS

The purpose of this Statement is (1) to protect the academic freedom traditional within the King Faisal Specialist Hospital & Research Centre (KFSH&RC), (2) to assist the KFSH&RC's investigators and the KFSH&RC itself in meeting their respective contractual responsibilities for research being carried on in the KFSH&RC; and (3) to guide Investigators in evaluating invitations to provide compensated consulting services outside the scope of their employment by the KFSH&RC, or to accept additional compensation for services within or incidental to the scope of such employment. This statement should be read in light of the KFSH&RC Code of Conduct and Policies on Conflicts of Interest.

Conflicts of Interest

1. Such an invitation frequently offers an Investigator the opportunity to enhance his scientific knowledge and perspectives. Thus, such invitations are welcome.

2. However, occasionally:

   a) The services contemplated by the proposed Consulting Agreement may materially relate to or draw on work (i) which the Investigator has done, is doing, or expects to do within the scope of his employment by the KFSH&RC and (ii) for which he has made, is making, or expects to make substantial use of facilities, materials, or other resources furnished by or through the KFSH&RC;

   b) Acceptance of the invitation may impose restrictions on the freedom of the Investigator to communicate with his colleagues about his consulting work, to publish reports on such work, to establish rights to own and use the fruits of the work, or to patent discoveries and inventions resulting from it; and

   c) Such restrictions may impinge as well on the rights and duties of both the KFSH&RC and other Investigators at the KFSH&RC, including obligations to sponsors of research already under way or contracted to be conducted at the KFSH&RC.

3. Thus, before accepting any proposed consulting agreement every Investigator shall disclose it to his Head/Chairman of the Unit/Department and will then submit it to the Chairman, Research Advisory Council (RAC) and request that the latter:

   a) Review the proposed agreement,
   b) Advise the Investigator as to its consonance with:
      (i) The Mission of the KFSH&RC
      (ii) The RAC Policy on Conflicts of Interest & Commitment;
      (iii) This Policy; and,

c) if the Investigator shall so further request, assist him in negotiating and drafting appropriate revisions of the proposal. In so doing, the Investigator may delete from the document all financial terms specified therein.

4. The Consulting Agreement must in any event:

a) Incorporate by reference and be subject to:

(i) KFSH&RC Intellectual Property Policy; and,

(ii) All additional obligations, if any, which the Consultant shall have at the time being under either or both of (a) the patent policies of any institution other than the KFSH&RC, and (b) any prior undertaking to conduct research, whether for the KFSH&RC, pursuant to another Consulting Agreement, or otherwise; and,

b) Impose no restriction on the freedom of the Consultant to discuss and disclose by publication or otherwise any research by him which shall make substantial use of any facilities, materials, or other resources furnished by or through the KFSH&RC .

5. The provisions of this Statement apply to all investigators, including those who are newly appointed to the professional staff. They must disclose their current consulting agreements to the RAC Chairman. Should any agreement contain provisions which do not conform to this statement or other applicable policies of the KFSH&RC, the investigator and RAC Chairman must act to make any necessary changes.

6. The Chairman of the Unit/Department will include a meeting between the Director, Office of Research Affairs (ORA) and individuals newly appointed to the staff as part of the appointment process for review of relevant KFSH&RC policies. The ORA Director will review with each applicant the applicant's consulting agreements to determine their conformance with the KFSH&RC policies and identify any potential conflict.

RESEARCH GRIEVANCE POLICY

In cases where Researchers and the Reviewing Committees cannot reach agreement through discussion regarding a recommendation, the Research Advisory Council (RAC) permits an appeal process according to the following:

1. The decision of the Research Ethics Committee (REC) or the Animal Care & Use Committee (ACUC) not to recommend approval of a proposal (or to suspend or terminate a previously approved proposal) may be appealed by the Principal Investigator (PI) only to the Committee that did not recommend approval. The RAC may not override such a decision by the REC or the ACUC.

2. The decision of the Clinical Research Committee (CRC) or the Basic Research Committee (BRC) not to recommend approval of a proposal (or to suspend or terminate a previously approved proposal) may be appealed by the PI to the RAC.

   2.1 The PI should submit an appeal in writing to the RAC Chairman, explaining and documenting the reasons for such a request.

   2.2 The RAC Chairman will review the appeal and take one of the following actions:

      2.2.1 Form an ad hoc appeal body made up of three members, one of whom should be a member of the Committee which did not recommend approval of the proposal, or

      2.2.2 If the PI did not present enough supporting evidence against the Committee's decision, inform the PI in writing that the decision made by the Committee is final.

   2.3 The appeal body will critically review the merit of the proposal and the comments of the Reviewers and the Committee's Members and may interview the PI. The body will forward its recommendation to the Chairman of the RAC, whose decision will be final.

RESEARCH CONTRACTS AND AGREEMENTS POLICY

1. Policy on Research Contracts and Agreements

There is a wide range of arrangements under which the KFSH&RC, or an individual within the KFSH&RC, may agree to undertake a research project on a specified problem, using KFSH&RC facilities and/or personnel, for a sponsor that provides funds to meet all or part of the costs of the project. These arrangements vary from a formal Research Contract to an Agreement or a simple letter.

The KFSH&RC encourages investigators directly associated with the KFSH&RC to seek and enter into arrangements which provide external financial support, through Research Contracts or other Agreements, for research in which KFSH&RC facilities are used, providing that such arrangements are compatible with KFSH&RC policies and regulations on research.

No member of the KFSH&RC shall engage in contractual research agreements without prior approval of the Chairman of the Research Advisory Council (RAC).

2. Procedural Guidelines and Principles

2.1 Preliminary Negotiation

2.1.1 After preliminary discussions by the Investigator with a potential sponsor, an Investigator is to seek written approval of both the project and related budget from the RAC;

2.1.2 This approval means that as a consequence of the proposed research:

a) the academic and financial interests of the KFSH&RC, the Investigator(s), and the public, are considered to be reasonably protected;

b) the normal teaching duties or other responsibilities of the Researcher(s) will not be affected adversely, or that acceptable adjustments to these duties have been made and budgeted for in the proposal, and as appropriate in the related departmental budget;

c) the existing KFSH&RC space and facilities will not be unduly burdened, or that needed additions to those have been budgeted for in the proposal; and

d) all direct costs and overhead charges have been considered and included as appropriate in the proposed budget.

2.2 Overhead Charges

Overhead charges are related to provision by the KFSH&RC of space, the use of equipment already owned by the KFSH&RC, heat, light, water, electricity and similar services, and the time of support personnel in supporting Departments.
The overhead charge shall be agreed to between the researcher and the Office of

Research Affairs on the basis of the following criteria:

2.2.1 The research proposal is initiated by the Investigator; the Investigator is free to use the funds in the way she or he thinks best in order to forward the proposed research; the title to any equipment purchased resides with the KFSH&RC; the research is academically acceptable (i.e. should lead to results suitable for publication in a refereed journal); and the Investigator is free to publish the results at her or his discretion, and there is no hold-back of funds subject to successful completion of all or any part of the project, including interim and final reports. No overhead need be charged.

2.2.2 The research contract or agreement is with KFSH&RC or a non-profit agency. The overhead charges specified in the regulations of the granting agency shall apply.

2.2.3 The research contract or agreement is with any other agency. Overheads may be charged at up to a maximum rate of 100 percent of the direct costs, depending on restrictions imposed by the contract or agreement, and normally shall not be less than 30 percent of the direct costs.

2.3 Office Of Research Affairs Responsibilities

The Office of Research Affairs (ORA) is to coordinate on behalf of the KSH&RC, arrangements made under this regulation. Grant applications and contract proposals are to be processed by the ORA according to established policies and guidelines.

2.4 Accounting

2.4.1 All incoming monies are to be made payable to the General Funds (11460801019669/2). Necessary accounting arrangements will be made by the Institute's Finance Department upon the request of the Office of Research Affairs.

RECOMBINANT DNA COMMITTEE GUIDELINES & POLICIES

The following policies and procedures have been adopted by the Recombinant DNA Committee (RDC), Research Advisory Council (RAC), King Faisal Specialist Hospital & Research Center (KFSH&RC)

1. RDC Charge

The RDC is mandated to evaluate for biosafety issues, all research proposals undertaken by members of, or within, KFSH&RC that involve recombinant DNA (RD) molecules. **RD 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 R D 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 RD research and prepares a report to the Chairman of the RAC.

The RDC reviews concerns involving the use of RD molecules at KFSH&RC.

The RDC makes recommendations to the RAC Chairman regarding any aspects of the KFSH&RC RD research, facilities, or personnel training.

The RDC adopts emergency plans covering accidental spills and personnel contamination resulting from RD research.

2. Responsibilities

KFSH&RC is responsible for providing a safe working environment for all KFSH&RC activities and for compliance with all applicable national and international regulations concerning R D research. Institutional responsibilities include the establishment and support of an RDA and the appointment of an institutional RD officer (RDO).

Chairman, Research Advisory Council (RAC)
Ensures that RDC is properly constituted and fulfills its requirements under the appropriate regulations, rules, etc.

Ensures that all members of the RDC are adequately trained in appropriate containment practices, secondary containment procedures, and accidental spill containment procedures to fulfill their responsibilities as members of the RDC.

Recombinant DNA Committee (RDC)
Advises the RAC Chairman, and Department Chairs on matters related to RD biohazards and biosafety within their respective areas of responsibility.

Develops, recommends, and implements policies and procedures for RD biological risk assessment and biological risk reduction throughout the Research Center.

Develops emergency plans for the containment and resolution of accidental spills and other related emergencies with an emphasis on risk reduction, personnel protection, and environmental protection.

Oversees all research and teaching activities involving RD including review and approval prior to initiation, annual reviews and updates, reviews of laboratory safety equipment and procedures, and certifications of compliance with all applicable rules and regulations governing the use of RD molecules.

As an agent of the institution, ensures all Lead Researchers (LR) are sufficiently trained in appropriate containment practices, secondary containment procedures, and accidental spill containment. A Lead Researcher is the researcher in-charge of the laboratory where the RD research is conducted.

Conducts investigations of serious violations or problems and makes recommendations to the Chairman of RAC for the resolution of continued non-compliance or serious infractions.

Recombinant DNA Officer (RDO)
Conducts periodic inspections of laboratories to ensure compliance with established containment procedures.

Investigates laboratory accidents and reports problems, violations, injuries and illnesses associated with RD research activities to the RDC.

Develops and implements emergency plans for handling accidental spills and personnel contamination.

Provides advice and assistance to the RDC and Lead Researchers concerning containment procedures and practices, laboratory security, recommended laboratory containment equipment, rules, regulations, and other matters as may be necessary.

Provides oversight and assurance that laboratory safety containment equipment is functioning properly including field testing and certification, where appropriate, of all biosafety cabinets.

Serves as a member of the RDC.

Office of Research Affairs (ORA)
Provides the necessary liaison between investigators, Lead Researchers, the RDC, granting agencies, and regulatory agencies.

Serves as the Office of Record for documentation involving RDC.

Provides all necessary documentation, forms, regulatory guidelines and regulations, etc., for principal investigators/Lead Researchers.

Lead Researcher
Ensures compliance with RAC and National Institutes of Health (NIH) guidelines and all conditions stated in the protocol approved by the RDC.

Submits protocol applications for all activities or modifications of activities involving RD materials and obtains approval by the RDC prior to initiation of the activities or modifications.

Ensures that all laboratory staff, including students, are trained in the accepted procedures in; laboratory practices, containment methods, disinfectant and disposal practices, utilization of all laboratory protective equipment and required actions in the event of accidental spill

Develops a laboratory safety plan, including an emergency action plan for accidents and spills, as an addendum to this manual, when required.

Ensures compliance with all shipping requirements for biological agents and RD molecules.

Ensures proper handling and disposal of all RD wastes.

Requests immunizations for all personnel when working with biological agents for which there is an effective vaccine available.

Maintains all biosafety equipment in appropriate operating condition. Decontaminates laboratory equipment prior to maintenance or disposal.

Maintains records of RD molecules, microorganisms and toxins used in the laboratory.

Laboratory Staff (Including Students)
Conducts no activities under the research protocol until the protocol is approved by the RDC and appropriate training is completed.

Follows all procedures and containment methods established for activities conducted.

Properly utilizes all laboratory protective equipment including proper clothing, personal protective equipment, and containment devices.

Reports all accidents and spills to the appropriate LR or the RDO as soon as possible.

Reports unsafe conditions to LR, the RDO or the RDC.

3 General RDC Approval Procedures

General Information
Anyone intending to perform any activities involving R D must submit a protocol to the RDC for consideration, including those which the investigator may feel are exempt from the NIH guidelines.

All protocols will be reviewed via a Triage System:

a. The LR estimates biohazard level of the research protocol.
b. The RDO reviews the protocol and either agrees with the LR, reclassifies the protocol or refers the protocol to full committee for reclassification.
c. The protocol will be reviewed according to the highest Biosafety Level estimation

Following review, one (1) of four (4) determinations will be made:

a. Approved – Protocol was approved without restrictions.
b. Approved subject to restrictions-Protocol was approved with some restriction. These restrictions will be attached. The project shall not be initiated until the restrictions have been removed or satisfied.
c. Disapproved – Protocol was disapproved. The reasons for disapproval are to be attached.
d. At any meeting, action on a protocol also may be deferred (i.e., the protocol tabled) pending receipt of additional information and/or clarifications. Any such tabled protocol shall be reconsidered at the next convened meeting after receipt of the requested information.

Multiple DNA segments can be incorporated into the same petition if they share a similar source and/or host.

LRS and Principal Investigators may be invited to present their protocols to the committee and to be available to answer committee questions. In such cases the LR and

Principal Investigators will be excused prior to discussion and voting.

General RDC Approval Procedures for Biosafety Level (BSL) [BSL – 1 and BSL – 2(see the NIH Guidelines)]

New and renewal protocol applications for agents requiring containment conditions of BSL – or BSL – 2 may be administratively approved by the RDO acting on behalf of the RDC. The full Committee will require only outcome notification and consultants may be called in as necessary.

Annual Review of BSL –1 and BSL – 2 protocols are conducted administratively by the RDO with notification of the RDC unless full Committee review is either requested by the administrative review or mandated by other such policy.

Investigators may appeal usage decisions by the RDO through petitioning of RDC followed by a full Committee hearing. The RDC may call a special meeting to expedite the appeal process if necessary.

Written descriptions of protocols that involve the use of R D molecules shall be made available to all RDC members, and any member of the RDC may obtain, upon request, full Committee review of those protocols.

General RDC Approval Procedures for BSL –3

New and renewal protocol applications for BSL – 3 agents are approved by the RDC, using a primary reviewer designated by the Chair , and then subject to other review as may be mandated by National and International regulations.

Protocols that have been approved pending receipt of clarification not involving major changes may be approved by the Chair with notification of the RDC.

Clarifications involving major changes are returned to the full Committee. The RDC determines whether a clarification should come back to the Committee at the time it grants approval pending clarification to the protocol.

Annual Review of BSL – protocols are conducted by the full RDC Committee**.**

Protocols involving the use of Class 4 Biohazards are not permitted

4. **Procedures for Conducting Continuing (Annual) Review of Protocols**

Information for Continuing Review
One month before the anniversary of a protocol, a continuing review questionnaire will be sent to the LR. The LR will be asked for a timely response.

If a response is not obtained, the protocol will be inactivated after an appropriate warning.

Screening
Screening procedures for BSL – 1 and BSL – 2

a. Once continuing review information is received for BSL – 1 & BSL – 2 protocols, it will be reviewed by the RDO specifically for:

   i). changes in the protocol
   ii). changes in regulations that require modification of the protocol.

b. If there are no changes, or minor changes then continuing protocol approval will be handled as a minor amendment.

c. If the RDO believes the committee should review the continuing information, the protocol will be handled as an amendment.

Screening procedures for BSL – 3:

a. Once continuing review information is received for BSL – 3 protocols, it will be reviewed by the full RDC Committee specifically for:

   i) changes in the protocol.
   ii) changes in regulations that require modification of the protocol.

b. Any changes in protocol/procedures will be handled as an amendment.

5. Procedures for Dealing with Allegations of Noncompliance (e.g., Laboratories or Actions Not in Compliance with the Appropriate Safety Guidelines, for Potential Protocol Violations, or for Work Being Done Without an Approved Protocol**)**

Allegations, preferably in writing, shall be made to the RAC Chairman. In all instances, these allegations shall be forwarded to the RDC Chair via the ORA. The RDC Chair is responsible for the receipt and disposition of all complaints. All allegations will remain confidential to the extent possible. When the complainant wished to be openly identified, the ORA will acknowledge receipt of the allegations to the complainant in writing.

The RDC Chair will appoint a subcommittee to determine if the complaint has sufficient substance to warrant a full investigation. All persons involved in the investigation will be

informed of the purpose of the investigation and the manner in which it will be conducted. In its investigation, the subcommittee will examine all pertinent documents and procedures, will interview involved personnel and will report its finding to the RDC Chair. If there is an indication of noncompliance, the RDC Chair will call for an investigation by the full RDC. If there is an indication of serious noncompliance the RDC **may recommend to the RAC Chairman to suspend impacted activities pending the outcome of the full investigation.** The full RDC investigation will be held during an executive session and all persons against whom the complaint is made will be given the opportunity to appear. Following the executive session and in open meeting, any recommendations from the investigation will be voted upon and RDC members will be given an opportunity to present minority views. The ORA will inform all parties involved, including the complainant, of the RDC findings.

Following the investigation, the Committee will recommend to the RAC Chairman any appropriate remedial action warranted and an appropriate specified time period for compliance.

6. Facilities and Program Review

As part of its ongoing duties, the RDC needs to assure itself that its facilities oversight is adequate and that its policies, procedures, petitions, and methods for conduction reviews are up to date.

Program Evaluation
The RDC should conduct a periodic self-evaluation of its overall program. This review will be an agenda item at least annually. This evaluation should include a review of all aspects of the RDC program, including, but not limited to, review of its Policies and Procedures document, its petition for requesting review of activities, its administrative procedures, previous year activities, and its protocol review procedures.

Facilities Walk-through
The RDC should conduct a periodic "walk-through" of the laboratories with approved RDC protocols. The purpose of this "walk-through" would be to maintain open communications between the RDC and Researchers and also to ensure that the LR and all associated laboratory personnel are complying with generally accepted safety practices, containment procedures, and approved protocols. These walks-through will make every attempt to minimize disruptions to laboratory functioning and should not cause intentional disruptions of normal laboratory safety conditions.

7. LR's Training Requirements

LRs must demonstrate that they are appropriately trained to safely conduct R D research.

This training may be demonstrated by either completing the KFSH&RC biosafety training

course or, if they have previous training, by completing a questionnaire in which such prior training is documents.

Any such documentation of previous training will be evaluated by a standing subcommittee of the RDC.

Prior to R D molecules use, all training documentation must be on file with the ORA.

LRs are responsible for insuring that their staff will be trained regarding the appropriate Biosafety Level policies and procedures to employ with each agent and that this training is documented.

8. Miscellaneous

Biosafety cabinets will receive field certification by the RDC:

1) before being put into service;

2) after major repairs and changes of the filter;

3) when relocated; and

4) no less frequently than annually.

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 118A.

The Office of Research Affairs (ORA) screens 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 summarizes your whole proposal, and it may be utilized 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 randomization), 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, fetuses, 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 (e.g., 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 coordinators, pharmaceutical company protocol monitors, etc) who require access to the record;
g) Summarize 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 (e.g., blood tests, urine tests, cultures, interviews, questionnaires, surgical procedures, cardiac catheterization, pulmonary function tests, X-rays, scans, etc);
    c) a brief description of the analyses that will be performed on the biologic or non-biologic (i.e. 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 (e.g., 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 clearly 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.

NOTE: 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.

GUIDELINES FOR CONSENT DOCUMENTS

NOTE: Only consent documents officially dated with inclusive Research Ethics Committee (REC) approval dates may be used in the conduct of human subject studies. When REC approval is granted, the consent documents will be stamped with an approval period. However, in the case of applications for sponsored support (i.e., NIH, KACST), consent documents will be held until official notification of funding is received. Under no circumstances may consent forms be used beyond their expiration date.

The forms (see Consent documents for Research Involving the Administration of Drugs, Use of Devices or Performance of Procedures, and for Research with No Direct Benefits to Participants) used in soliciting consent must provide, in writing, all of the information that the subject would reasonably want about the study and the extent of his/her involvement in it.

An investigator shall seek such consent only under circumstances that provide the prospective subject, or the representative, sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence.

The informed consent, whether oral or written, may not include any exculpatory language through which the subject, or the representative, is made to waive, or appear to waive, any of the subject's legal rights, or releases, or appears to release, the investigator, the sponsor, the Institution or its agents, from liability for negligence.

By completing these documents, as suggested below, all of the international requirements for informed consent should be fulfilled.

Research Participant Information Sheet: This information sheet explains details of the research that are unique to the particular study and therefore must be written by the Principal Investigator. The Research Participant Information Sheet must incorporate the following components, including the appropriate subject headings for each component:

TITLE OF PROJECT: Place at the top of the first page of the consent document.

A. PURPOSE OF THE RESEARCH:

Begin by writing "You are being asked to participate in a research study. The purpose of this study is …". Then state "You qualify for participation in this study because…".

B. DESCRIPTION OF THE RESEARCH:

Must be written in language that is fully understandable to an individual with a sixth-grade education. Thus, scientific terms must be defined in language easily comprehensible to the layperson, (see Glossary of Lay Terms for Use in Preparing Informed Consent Documents).

1) describe the study design.
2) describe specifically what will be required of the subject.

3) describe which procedures or tests are being performed solely for research, and which are being done for clinically indicated reasons. Only describe (in detail) those procedures or tests (or components thereof) that are being done for research purposes.
4) indicate if the drug, device or procedure is approved by the Food and Drug Administration or similar agencies, or not approved for the purpose proposed in this study.
5) indicate the approximate number of subjects to be enrolled.
6) indicate the duration of the subject's participation.

NOTE: Under most circumstances patients must be enrolled in a study prior to **any** screening evaluations. This must be reflected in the consent form. If it is found that the patient does not qualify, then he/she should be terminated from the study. The rationale for enrolling patients prior to evaluation is that it is inappropriate for patients to have to be responsible for the costs associated with such evaluations (e.g., examinations and tests), subjected to any risks associated with screening procedures, or to be personally responsible for the costs associated with treatment for any adverse reactions.

C. POTENTIAL RISKS AND DISCOMFORTS:

Describe all potential risks and discomforts whether major or minor. Estimate the likelihood and severity of such risks and describe the reversibility of adverse reactions. If blood drawing is included in the study, be sure to indicate the risks involved (e.g., fainting, pain, hematoma, etc). A statement should be included, if applicable, that participation may result in currently unforeseeable risks to the subject (and possibly the fetus or embryo, in the event of pregnancy).

D. POTENTIAL BENEFITS:

Describe the potential benefits of participation for the subject, the general benefits for science, the population at large, or other patients with similar diseases. Estimate the likelihood of such benefits, followed with Allah's will. Do not include information regarding compensation or procedures or medications provided at no cost.

E. ALTERNATIVES TO PARTICIPATION (where applicable):

The Principal Investigator should state: "The following are possible alternatives to participation…" and/or "Treatment comparable to that being proposed in the context of this study is/is not available to you outside of such a study." If the study does not involve treatment and there are no alternatives, simply state "The alternative is not to participate."

F. COSTS/REIMBURSEMENTS:

Indicate:

1) whether the subject will incur any costs by participating, and
2) whether the subject will receive any reimbursement for time and expenses.

G. TERMINATION OF PARTICIPATION:

Include the following: "You may discontinue participation in the study at any time without penalty or loss of benefits to which you are otherwise entitled."

When applicable, describe potential consequences of a subject's decision to withdraw and procedures for early termination. Explain circumstances under which participation may be terminated by the investigator without the subject's consent.

H. COMPENSATION/TREATMENT:

You may include **ONE** of the following standard statements, as appropriate:

For minimal risk protocols: "If you believe that you have suffered an injury related to this research as a participant in this study, you should contact Dr _____ at telephone # _____.

For more than minimal risk protocols: If the subject might receive direct benefit from participation: "In the event of injury resulting from your participation in this research study, short-term hospitalization and professional attention will be made available to you at your expense. Financial compensation from KFSH&RC will not be provided. If you believe that you have suffered an injury related to this research as a participant in the study, you should contact Dr _____ at telephone # _____.

For more than minimal risk protocols, if the subject is not expected to receive direct benefit (eg, controls): "In the event of injury resulting from your participation in this research study, short-term hospitalization and professional attention, if these are required, will be provided at the KFSH&RC, at no cost to you. Financial compensation from KFSH&RC will not be provided. If you believe you have suffered an injury related to this research as a participant in this study, you should contact Dr _____ at telephone # _____.

I. VOLUNTARY PARTICIPATION:

Include the following: "Participation in the study is voluntary. If you decide not to participate this will not affect your ability to receive medical care at KFSH&RC, or to receive any benefits to which you are otherwise entitled."
"Any new information that develops during this study, which might affect your decision to participate, will be given to you immediately."

"A signed copy of this consent form will be given to you."
The entire section of voluntary participation should be highlighted.

J. CONFIDENTIALITY:

Include the following: "Your identity as a participant in this research study will be kept confidential in any publication of the results of this study. Your medical record in connection with this study will be kept confidential to the extent permitted by the law. However, your medical record may be reviewed by government agencies or the

agency sponsoring this research, if required by applicable laws or regulations."

K. CONTACT PERSON(s):

Include the following: "If you have any questions, at any time, about this research, please contact Dr _____ at telephone # _____. If you still have questions, you may discuss them with a member of the section of Assurance & Compliance, Office of Research Affairs, telephone # _____.

INSTRUCTIONS TO INVESTIGATORS

There are circumstances under which some of the elements in this Form may be altered or waived (see Request for Modification of Informed Consent) and/or requirements for the consent form to be signed may be waived, (see Request for Modification in Documentation of Informed Consent). 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, and middle school age children may provide a written assent. A witness signature is only needed when the subject or the subject's guardian cannot read. The English and Arabic versions of the consent form should be written side-by-side on the page.

GUIDELINES FOR PROPOSAL 'AUTHORSHIP'

1. Proposals that originate from KFSH&RC

   1.1 The credit for being on a proposal should be based on:
   a) a substantial contribution to conception or design, or to drafting of the proposal or revising it critically for important intellectual content, as well as,
   b) taking responsibility for the proposal by endorsing the submitted version.

   Participation solely in the following is not sufficient:
   a) acquisition of funding
   b) referring patients
   c) supplying materials/samples
   d) general supervision of the research group
   e) technical assistance
   f) statistical data analysis

   1.2 Being a Principal Investigator (PI), Co-principal investigator (Co-PI) or co-investigator should be a joint decision of the investigators. However, the PI should be at the Associate Consultant/Consultant level for interventional clinical proposals and should be a permanent employee of KFSH&RC for all proposals. In the event the PI leaves the Institution, a suitable replacement, fulfilling the above criteria, should be nominated by the departing PI, and approved by the Department Chairman and the RAC.

   1.3 The PI is responsible for:
   a) all reporting to the Research Advisory Council in a timely manner;
   b) overall management of the project;
   c) data and consent forms to be submitted for review if required; and
   d) authorship/order of authorship for all resulting publications.

2. Proposals that originate from outside the KFSH&RC

   2.1 For multi-centre study proposals where the PI is from an institution other than KFSH&RC**,** a KFSH&RC Primary Investigator and a KFSH&RC co-investigator(s) should be designated. The credit for being on such a proposal should be based on:
   a) extensive review of the proposal to ensure that it complies with RAC Guidelines/Standards, with appropriate revision, if required;
   b) commitment to carrying out the KFSH&RC part of the proposal in a timely manner; and
   c) taking responsibility for the KFSH&RC part of the proposal by endorsing the submitted version.

   2.2 Being a KFSH&RC Primary Investigator or KFSH&RC Co-investigator should be a joint decision of the KFSH&RC investigators and the external PI.

   2.3 The KFSH&RC Primary investigator is responsible for:
   a) all reporting to the Research Advisory Council in a timely manner;
   b) overall management of the KFSH&RC part of the project; and
   c) data and consent forms to be submitted for review if required.

GUIDELINES FOR EXPEDITED REVIEWS

Proposals that originate from KFSH&RC

1. 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-analyzing 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. 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 fulfill 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.

Proposals that originate outside KFSH&RC

1. 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. 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 fulfill 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.

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.

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. Approve the proposal as submitted, or
2. Conditionally approve the proposal, or
3. Obtain further information, or
4. Submit the proposal to the full Committee for review.
5. 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.

Criteria for Expedited Review by the Research Ethics Committee

Research that can be considered to present minimal risk to subjects is eligible for expedited review. Minimal risk means that the risk of harm anticipated in the proposed research is no greater than that ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

Categories of new and continuing research that may be reviewed by the REC through an expedited review procedure (as revised by Office of Protection from Research Risks, USA, 11/98).

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   (a) from healthy, non pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   (b) from other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.
   (a) hair and nail clippings in a nondisfiguring manner;
   (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   (c) permanent teeth if routine patient care indicates a need for extraction;
   (c) excreta and external secretions (including sweat);
   (d) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution on the tongue;
   (e) placenta removed at delivery;
   (f) amniotic fluid obtained at the time of rupture of the membrane prior to, or during, the labor;
   (g) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques;
   (h) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(i) sputum collected after saline mist nebulisation.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
(b) weighing or testing sensory acuity;
(c) magnetic resonance imaging;
(d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened REC as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
(b) where no subjects have been enrolled and no additional risks have been identified; or
(c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the REC has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Criteria for Expedited Review by the Animal Care & Use Committee

All research on live vertebrate animals other than those which the Animal Care and Use Committee (ACUC) has the authority to review and approve by expedited review (and elect to review and approve by expedited review), must be reviewed at a convened meeting of the full ACUC.

Research that can be considered to present minimal pain, discomfort or distress (category A and B in the table below) maybe eligible for expedited review.

Category*	Level of pain, discomfort and distress
A	The protocol involves no pain, discomfort, or distress greater than that produced by routine injections or venipuncture. Includes simple invasive procedures (e.g., injection, blood sampling), terminal anesthetic surgery, collection of tissues preceded by standard euthanasia, behavioral testing without stress.
B	The protocol involves minor short-term pain, discomfort, or distress. Includes anesthetic survival surgery without significant postoperative and/or functional deficit (e.g., gonadectomy, exploratory abdominal surgery), implantation of chronic catheters, induction of minor behavioral stress, and physical restraint in excess of that required for routine procedures classified under Category A.
C	The protocol involves chronic maintenance of animals with a disease/functional deficit and/or procedures inducing moderate to significant but tolerable pain, discomfort, or distress. Includes major anesthetic survival surgery with significant postoperative pain and/or functional deficit (e.g., orthopedic surgery on femur, amputation, invasion of large muscle mass); tumor inducement, radiation sickness, toxicity testing, induction of moderate to significant behavioral stress.
D	The protocol involves pain, discomfort, or distress (greater than that attending routine injections) which cannot/will not be alleviated/minimized through the administration of appropriate anesthetic, analgesic, or tranquilizer drugs.

*These categories are derived from the United State Department of Agriculture (USDA) reporting requirements.

GUIDELINES FOR RESEARCH PROPOSALS OF EXTERNAL POSTGRADUATE STUDENTS

Proposal Format

The proposal is acceptable in the format that is submitted to the Training & Education Committee (TEC). However, it should include the following:

1. an abstract in English;
2. an outline of the exact contribution of KFSH&RC (staff, facilities, funding, etc.); and
3. applicable forms, such as, the Cover Page, Investigators' Assurance Form, Budget Form, Hazards Forms, Consent Form, Proposal Clearances Form, and Animal Care & Use Form.

Research Proposal Involving Human Subjects or Vertebrate Animal

All such proposals need approval by the Research Ethics Committee (REC) or the Animal Care & Use Committee (ACUC) of the Research Advisory Committee (RAC), regardless of external approval. This can be through a full or expedited review, depending on the nature of the involvement.

Funding

1. proposals that are totally funded by an external sponsor will be exempted from review by the Clinical Research Committee (CRC) or the Basic Research Committee (BRC), but need to be certified as such by the RAC. They will be presented to the BRC or the CRC (whichever is applicable) for information.
2. proposals that will be funded, in part or completely, by KFSH&RC are processed via the expedited review process, provided that the cost to KFSH&RC does not exceed SR 20,000 per year, and the total KFSH&RC personnel commitment does not exceed 0.25 FTE.
3. proposals that require funding or personnel commitment in excess of what is mentioned in point (2) above, will require full review by BRC or CRC (whichever is applicable).

Progress and Final Reports

Progress and Final reports, using the RAC format, are a requirement for all research proposals.

GUIDELINES FOR MANUSCRIPT AUTHORSHIP

This one-page summary was taken from the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: International Committee of Medical Journal Editors" which has recently been republished in the New England Journal of Medicine [336(4):309-15,1997 Jan 23], the Annals of Internal Medicine [126(1):36-47, 1997 Jan 1] and the Canadian Medical Association Journal [156(2):270-85, 1997 Jan 15] among others.

Authorship

Authorship credit should be based only on substantial contributions to:

a) either the conception or design or else analysis and interpretation of data and to
b) drafting the article or revising it critically for important intellectual content and on
c) final approval of the version to be published.

All three conditions must be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not sufficient for authorship. Each author should have participated sufficiently in the work to take public responsibility for it.

Acknowledgments

The following are not considered as substantial contribution for authorship and therefore do not warrant authorship. However, they can be acknowledged. At an appropriate place in the article one or more statements should specify the following:

a) contributions that need acknowledging but do not justify authorship, such as general support by the department chair, providing samples and acquisition of funding;
b) acknowledgments of technical help;
c) acknowledgments of financial and material support, specifying the nature of the support; and
d) financial relationships that may pose a conflict of interest.

GUIDELINES ON ACCESS TO MEDICAL RECORDS FOR RESEARCH

For the purpose of this policy, "Medical Records" means all data obtained on patients or their relatives during their evaluation, treatment, and follow up at KFSH&RC regardless of the media used for recording; and include data of "history and physical" and of all investigations such as laboratory, cytology, histology, radiology, special laboratory, etc.

1. The Research Advisory Council (RAC) recognizes that:

   1.1 Medical Records based research, through the analysis of databases of health information, offers the potential to improve the quality of health care delivery and the effectiveness of health care policies. At the same time, the analysis of personally identifiable health information from many individuals raises concerns about privacy and confidentiality.

   1.2 Although some of the data in Medical Records are obtained as part of approved research projects, most data are obtained as part of routine medical care with no prior intention for research or scientific reporting.

   1.3 It is ethically unacceptable to obtain data, totally or in part, for the purpose of research or scientific reporting without prior approval of the Research Advisory Council; data so obtained should not be published.

   1.4 The data in Medical Records are usually obtained by various caregivers in various specialties, and it is often difficult, if not impossible, to determine the exact contribution of the various parties to the collection of a given piece of data (the physician who ordered the MRI vs the radiologist who read it; the physician who referred the patient to surgery vs the surgeon vs the pathologist).

   1.5 Providing medical care, referring patients, or providing patients' samples is not by itself a valid justification for inclusion as a coauthor on a publication or a co-investigator on a research proposal.

2. Therefore, and in order to protect patients rights, facilitate and improve quality of research, and prevent covert use of patient care resources in research, the RAC establishes the following guidelines:

   2.1 If the data in Medical Records were obtained as part of an RAC-approved prospective research study they can only be accessed for research/reporting purposes by the investigators of the research study or their designee.

   2.2 If the data were obtained as part of routine patient care and there is no related RAC approved research study, the RAC can permit an investigator(s) to review the Medical Records for research even if the investigator(s) did not contribute to obtaining the data, provided that the investigator(s) submit a research proposal to RAC and that RAC determines that the investigator(s) are ethically and scientifically competent in collecting and analysing the data and will adhere to the RAC rules.

   2.3 In general, the Research Ethics Committee (REC) can permit the access to Medical Records for research if it determines that the benefits of the study outweigh the risks, as long as the patient has not specifically indicated his/her refusal to have the Medical Records reviewed for research. The REC may require, depending on the risk to patients and their families that an informed consent is obtained prior to permitting the access of the investigators to the Medical Records.

COVERAGE OF PAGE CHARGES, REPRINTS, AND COLOUR PRINTS COST

1. The RAC covers page charges and reprints cost of all manuscripts (full paper, reviews, letters to the Editor), provided:

   (i) the manuscript is approved by the RAC to be submitted for publication, and
   (ii) the manuscript is the result of an RAC approved project,

   OR

   (i) the manuscript is approved by the RAC to be submitted for publication, and
   (ii) the first and corresponding author(s) is/are KFSH&RC employees at the time the work was done (this should be clear from reading the manuscript), and
   (iii) the Journal Impact Factor (JIF) is ≥ 3.

2. Only the cost of the minimum number of reprints that can be ordered will be covered.
3. Manuscript submission fees and postage cost are not covered by the.
4. Page charges and reprint cost of abstracts and book chapters are not covered by the RAC.
5. The cost of colour prints is covered by the RAC, provided:

   (i) the manuscript fulfills the conditions in (a) or (b) in point 1 above;
   (ii) the JIF is ≥ 3,
   (iii) the need for colour prints is justified by the author(s) in writing, to the satisfaction of the RAC.