RESEARCH ADVISORY COUNCIL

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of research or scientific reporting without prior approval of the Research Advisory Council; data so obtained should not be published.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 specialities, 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 coinvestigator 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.