

RESEARCH ADVISORY COUNCIL

POLICY ON INTEGRITY IN THE PERFORMANCE OF RESEARCH

Preamble

In any human endeavour, including scientific research, there are individuals who, for various reasons, do not adhere to appropriate norms of behaviour. 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 publicised 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.

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 generalizable 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 judgements 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:

- 1 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;
- 2 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;

- 3 secure necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence, and
- 4 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.

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.

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.

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 which 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:

- 1 the withdrawal of all pending involved abstracts and papers;
- 2 notification of editors of journals in which involved research was reported;
- 3 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
- 4 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.

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.

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.