#### Health Authority - Abu Dhabi



هيئة الصحة - أبوظبي

**HAAD External Policies** 

Title: Abu Dhabi Health Research Council

Reference Number: PHP/PHR/R01 Issue Date: February 2010 Next Review Date: February 2012

# **CHAPTER 1. INTRODUCTION**

## 1 Purpose

1.1 This policy establishes the Abu Dhabi Health Research Council and sets out its objectives, functions and governance arrangements.

### 2 Background

- 2.1 The Health Authority Abu Dhabi (**HAAD**) is the authority responsible for regulating human subjects research in the Emirate of Abu Dhabi.
- 2.2 HAAD wishes to establish the Abu Dhabi Health Research Council to oversee the development of the Abu Dhabi Health Research Strategy and to advise HAAD on all aspects of human subjects research in the Emirate of Abu Dhabi.
- 2.3 The Council will be the principal body for supporting human subjects research, providing advice on human subjects research, setting standards of ethical behaviour in human subjects research, and regulating the conduct of human subjects research in the Emirate of Abu Dhabi.

### 3 Scope

- 3.1 This Policy sets out the role, function, membership and governance arrangements of the Abu Dhabi Health Research Council.
- 3.2 This Policy applies in addition to other HAAD policies and standards relating to public health, and is without prejudice to the requirements of all other federal laws applicable to human subjects research.

#### 4 Related Policies

- 4.1 The following HAAD Policies are closely related to this one
  - 4.1.1 "Licensing Requirements for Institutional Human Subjects Research" (Ref PHP/PHR/R02).
  - 4.1.2 "Policy Governing Research Involving Human Subjects" (Ref PHP/PHR/R03).

# 5 Interested Parties

5.1 This policy is of relevance to all individuals and institutions involved with human subjects research in the Emirate of Abu Dhabi.

#### CHAPTER II. THE ABU DHABI HEALTH RESEARCH COUNCIL

#### 6 The Abu Dhabi Health Research Council

6.1 There shall be a body known as the Abu Dhabi Health Research Council (the Council).

### 7 The Objectives of the Council

- 7.1 The Objectives of the Council shall be
  - 7.1.1 to advise the Chief Executive Officer "CEO" of HAAD on the Abu Dhabi Health Research Strategy,
  - 7.1.2 to identify the health research needs of the Abu Dhabi population,
  - 7.1.3 to ensure that health research in the Emirate of Abu Dhabi meets the highest international scientific and ethical standards,
  - 7.1.4 to administer funds granted to the Council for the purpose of implementing Abu Dhabi health research policy,
  - 7.1.5 to promote research that addresses the health research needs of the Abu Dhabi population,
  - 7.1.6 to establish policies that attract, develop and retain world-class clinicians and researchers at Abu Dhabi health care facilities and research institutions,
  - 7.1.7 to contribute to the productive diversification of the Abu Dhabi economy, and
  - 7.1.8 to evaluate progress in meeting the Objectives of the Council and the goals set out by HAAD to the Abu Dhabi Health Research Strategy.

### 8 The Functions of the Council

- 8.1 The functions of the Council shall be
  - 8.1.1 to oversee the development and execution of the Abu Dhabi Health Research Strategy,
  - 8.1.2 to review on a regular basis all health research regulations, policies and standards developed by HAAD,
  - 8.1.3 to carry out from time to time a review of the productivity and effectiveness of the Abu Dhabi Health Research Strategy,
  - 8.1.4 to take appropriate steps to promote human subjects research in the Emirate of Abu Dhabi,
  - 8.1.5 to ensure the development and application of appropriate assessment standards by committees or subcommittees that assess health research proposals,

- 8.1.6 To carry out the functions as delegated to the Council by HAAD's CEO or assigned thereto under the Policy "Licensing Requirements for Institutional Human Subject Research" (Ref PHP/PHR/R02) & the federal laws.
- 8.1.7 to exercise any other functions conferred on it in writing by HAAD's CEO.
- 8.2 The Council must exercise these functions in the manner that it considers best designed to achieve the fulfilment of its Objectives.

### 9 Reporting

9.1 The Chairman of the Council must report annually to HAAD's CEO on the Council's performance measured against its Objectives.

#### 10 Governance

- 10.1 The Council must act in accordance with any direction issued from time to time by HAAD through the HAAD's CEO.
- 10.2 The Council must follow the Rules of Procedure set out in Appendix A.
- 10.3 The Council may, by a majority vote of Council Members and with the approval of HAAD's CEO, amend the Rules of Procedure, in which case the amended rules will be substituted for Appendix A.

### 11 Administration

11.1 The Medical Research Section at HAAD will provide the Council with administrative resources and support.

# 12 Membership of the Council

- 12.1 The Council Members will be appointed by a decision of the HAAD Chief Executive Officer.
- 12.2 The Council will consist of the following members
  - 12.2.1 the Council Chairman,
  - 12.2.2 the Council Vice Chairman,
  - 12.2.3 the Council Secretary,
  - 12.2.4 one member from the Ministry of Presidential Affairs,
  - 12.2.5 one member from SEHA,
  - 12.2.6 one member from the General Authority of Islamic Affairs and Endowment (Awqaf)
  - 12.2.7 one member from the Abu Dhabi Education Council or Ministry of Higher Education and Scientific Research (MOHESR), and

- 12.2.8 at least four, but no more than ten, Expert Members.
- 12.3 To be eligible for appointment as an Expert Member, a person shall have expertise in one or more of the following fields
  - 12.3.1 healthcare research and training,
  - 12.3.2 the healthcare professions, including the medical, nursing and allied health professions with post-graduate medical training,
  - 12.3.3 public health research involving human subjects,
  - 12.3.4 the healthcare industry, including the pharmaceutical, biotechnology and gene therapeutics industries,
  - 12.3.5 the ethics of human subjects research,
  - 12.3.6 the funding of human subjects research,
  - 12.3.7 applicable laws and regulations governing human subjects research.

#### 13 Vacancies

- 13.1 Any member of the Council may at any time be removed from office by the HAAD's CEO for disability affecting performance of duty, bankruptcy, neglect of duty, misconduct, or for being unfit for the office.
- 13.2 Any member of the Council may at any time resign his or her office by providing written notice to the Chairman.
- 13.3 If any member of the Council dies or resigns or is removed from office, the vacancy shall be filled in the manner in which the appointment to the vacant office was originally made.
- 13.4 The powers of the Council shall not be affected by any vacancy in its membership without prejudice to the Rules of Procedures under Appendix A .

# **CHAPTER III. COMPLAINTS & APPEALS**

# 14 Complaints

- 14.1 Any person who is not satisfied with an action of the Council, or a failure of the Council to act, may complain to HAAD.
- 14.2 HAAD will address complaints in accordance with the HAAD Complaints and Appeals processes.

# 15 Appeals

- 15.1 Any decisions of HAAD over the complaint shall be subject to appeal to HAAD's Appeals Committee.
- 15.2 HAAD will consider appeals in accordance with its Appeals Committee terms of formation.

#### **CHAPTER IV. GLOSSARY OF TERMS**

In this Policy the following terms shall have the meanings given to them below -

Abu Dhabi Health Research Council means the body of that name established by this Policy.

Abu Dhabi Health Research Strategy

means the strategy approved by the Health Research Council to meet the health research needs of the Abu Dhabi population.

Council means the Abu Dhabi Health Research Council.

**Council Member** means any person appointed to be a member of the Council, in the period during which he or she holds that office.

**Human Subjects Research** means any activity falling within one or more of the following categories -

- Studies of a physiological, biochemical, or pathological processes, or of the response to a specific intervention

   whether physical, chemical or psychological – in healthy subjects or in patients.
- Controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalisable response to these measures against a background of individual biological variation.
- Studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures.
- Studies concerning human health-related behaviour in a variety of circumstances and environments.

**Objectives** means the objectives of the Council as set out in this Policy.

**Rules of Procedure** means the rules set out in Appendix A of this Policy.

#### **Appendix A. RULES OF PROCEDURE**

### **Council Meetings**

- (1) Council meetings will take place at least once per year to establish policies, objectives, and guidelines; create committees, as necessary, to review proposals and research plans; evaluate progress towards objectives; and consider other matters brought before the Council, as needed.
- (2) Additional meetings may be held where necessary in one of the following ways:
  - (a) In person at the regular meeting location, with the same quorate requirements
  - (b) Via email correspondence or telephone or video conference, with the same quorate requirements
- (3) Notice of meetings, meeting agenda, and minutes of meetings will be circulated by the Council Secretary. The agenda will be developed by the Chairman and members will receive an agenda, briefing materials and other documentation as early as possible but at least seven days in advance of meetings.
- (4) Members shall declare to the Committee any interests they may have in relation to research proposals, applications for ethical review, or any other matter for consideration at that meeting.
  - (a) Such a declaration may be made orally at the meeting, prior to the matter being considered, or in writing to the Chair prior to the meeting.
- (5) Confidentiality of proceedings
  - (a) Council members need to be able to discuss freely the proposals and research plans submitted to them. For this reason Council meetings shall be held in private, and members shall be encouraged to raise any matters of concern.
  - (b) The terms and conditions of appointment for members include requirements to keep confidential the business of the Council.

#### Voting

- (6) The quorum for meetings of the Council is seven members, including the following:
  - (a) The Chairman or, if unavailable, the Vice Chairman;
  - (b) At least two expert members; and
  - (c) At least four other members.
- (7) A member who is unable to attend in person can join the meeting via telephone or video link. This member shall also be counted for the purpose of the quorum. Signatures of quorum members attending via telephone or video link can be obtained retroactively.
- (8) A member can appoint a deputy among the Council's members who shall be counted for the purpose of the quorum if he/she attends in his place.
- (9) A member who is unavailable to attend a meeting may submit comments in writing on any agenda item.
- (10) The following shall not be counted for the purpose of the quorum:
  - (a) Advisors or referees;
  - (b) Members who are yet to arrive at the meeting, or who have left early;
  - (c) Members who submit written comments but do not attend or appoint a deputy; and
  - (d) Council Secretary.
- (11) The Chair is responsible for the conduct of the business and for ensuring that the Council reaches clearly agreed decisions on all matters. Where the Chair is unavailable, the meeting shall be chaired by the Vice-Chair.
- (12) All members present, both expert and lay, shall be allowed reasonable opportunity to express relevant views on matters on the agenda.
- (13) The meeting shall reach unanimous decisions by consensus wherever possible. Where a consensus is not achievable a formal vote shall be taken by a counting of hands. The decision of the Council shall be determined by a simple majority of those members present and entitled to vote in a quorate meeting.
- (14) Where any member wishes to record his/her formal dissent from the decision of the Council, this shall be recorded in the minutes.
- (15) Where a quorum is not present, the Council must not commence business, continue or conclude any discussion with the purpose of determining a decision by the Council.
- (16) A Council meeting, or part of the meeting, at which a quorum of members is not present, may proceed with any other business on the agenda, provided that the Chairman or Vice Chairman and at least one other member is present.

- (17) The Chairman will issue resolutions based on the minutes of the Council. A summary of discussions will be provided by the Chair to the Secretariat. Committee members will be expected to demonstrate fairness and a commitment to in-depth examination of matters under review.
- (18) A Record of Meeting will be prepared and circulated by the Secretariat within five (5) working days after each meeting. These will be certified for accuracy by the Chair. Records of Meetings will be kept to the minimum of detail required to summarize effectively the proceedings and to reflect any Committee's recommendations and advice.
- (19) The minutes shall be treated as confidential to the Council and not routinely disclosed to applicants or the general public. For the purposes of Council governance, copies of minutes shall be made available on request to the HAAD CEO and/or HAAD Chairman.

#### **Committees**

- (20) The Council may form committees to carry out the following activities:
  - (a) Evaluate Abu Dhabi's medical research needs and identify research priority areas;
  - (b) Provide ethical review of human subjects research proposals;
  - (c) Conduct peer review of research grant applications or other research funding proposals;
  - (d) Consider significant amendments to Council policies;
  - (e) Evaluate results and productivity of Abu Dhabi health research programs;
  - (f) Any other business that requires action or attention of the Council.
- (21) Committees shall consist of no less than two people approved by the Council.
- (22) A committee terms of formation shall determine rules of procedure thereof & the delegated authority to act on behalf of the Council on the matters delegated to the committee under paragraph (20) above. Decisions taken by the committee shall be reported to the Council and require ratification by the Chairman. Decisions made by a committee on behalf of the Council may be subsequently reversed by the Council.

#### Participation in the Council's Meetings by Non Members

(23) The Chair of the Council may invite persons who are not Council Members to attend and participate in a Council meeting when s/he considers that this is likely to be relevant and useful to the Council's deliberations.