

Health Research Streuture & Procedures



Health Research Committee Research Technical Suupport Team 2009

Prepared by:

Dr. Ahmed Omran
Coordinator, Health Research and Studies

Reviewed by:

Research Technical Support Team

Approved By:

Health Research Committee

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1. Background

Ministry of Health has conducted several priority surveys last few years such as the National Non-communicable Diseases Survey (EMAN Survey), Nutrition Survey and Dental Health Survey. Meanwhile, there are some research and publications in different aspects of health system assessment through individual efforts and contributions.

Recognizing the importance of institutionalizing health research in the Ministry of Health, a central Health Research Committee was established in 2005, which is chaired by the Undersecretary. From which, a Research Technical Support Team and three sub-committees; Primary Health Care, Secondary Health Care and College of Health Sciences, were established. The main functions of the central Health Research Committee are; adoption of health research policies / strategies and priorities in the MOH, monitoring health related research and ensuring its adherence to medical ethics, research capacity building, approval of research budget and grants, and cooperation with local, regional and international organizations.

A mechanism for compiling and recording the number of health research conducted was established last year. Accordingly, lists of all dissertations done by MOH staff as part of their master degree courses in different fields and Family Practice Residency Program residence were created. In contrast to previous research committees within the ministry, some funds were attached to the current central committee. A plan to establish a Medical Research and Evidence Group in the existing Medical Review Office has been submitted recently to the Civil Service Beauru.

2. Key Stakeholders in Health Research

- AMA International University.
- Arabian Gulf University.
- Bahrain Centre for Study and Research.
- Bahrain University.
- Central Informatics Organization (C.I.O).
- Ministry of Health including College of Health Science.
- Royal College of Surgeons Medical University of Bahrain.
- Royal Medical Services Hospital (BDF Hospital).

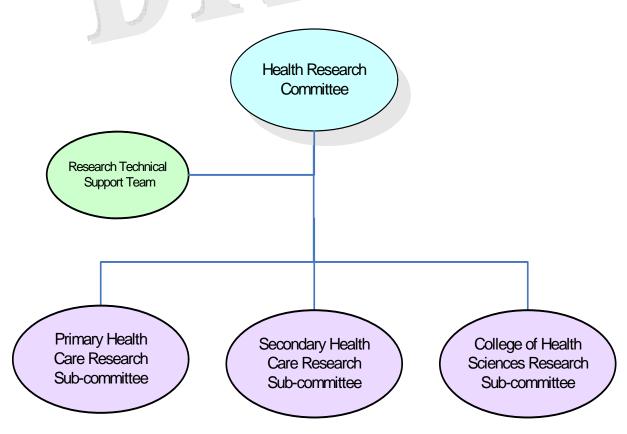
3. Health Research Structure in the Ministry of Health

Health research was identified as one of the twelve strategic goals in the document "Bahrain Health Strategy; Framework for Action" under the Strategic Goal No. 10: Education, Research and Development "Develop the role of the health system in

education, research and development in Partnership with other agencies, and focus on health research for development" (MOH, 2002).

To implement this strategic goal, MOH established a central Health Research Committee (HRC) in 2005 by a ministerial order No. (19) (Annex I), from which, a Technical Support Team (RTST) (Annex II) and three sun-committees; Primary Health Care (PHCRC), Secondary Health Care (SHCRC) and College of Health Sciences (CHSRC), were established (Annex III, IV, V). Furthermore, the Ministry of Health established the first Branch for Cochrane center in the Arab World, Bahrain Branch of the UK Cochrane Centre was created after a joint meeting held in Bahrain on 9 January 2005 and hosted by the Bahrain Ministry of Health.

3.1 The Organization Structure of Research Activities at the Ministry Of Health



3.1.1 Functions of the HRC:

• Adoption of health research policies, strategies and priorities in the MOH.

- Monitoring health related research and ensuring its adherence to medical ethics.
- Research capacity building for the MOH employees
- Documentation and dissemination of research results.
- Approval of research budget and grants.
- Cooperation with local, regional and international organizations

A Research Technical Support Team (TST) with three sub-committees (primary health care (PHC), secondary health care (SHC) and college of health sciences (CHS) were established under the HRC.

3.1.2 Functions of the RTST:

- Supervision and monitoring of national health surveys and the provision of technical support.
- Provision of technical support to research sub-committees.
- Approval of research proposals of MOH employees and the provision of technical support.
- Approval of research proposals submitted from other organizations and academic institutions intending to use MOH data or facilities.
- The provision of advice regarding medical ethics to research subcommittees and to researchers from other health organizations and academic institutions who intend to conduct research by using ministry data or facilities.
- National Capacity Building in the field of health research.
- Coordination with the HRC to identify ministry's research needs and priorities.
- Advise the HRC regarding requests for Research Grants or Financial support.
- Other responsibilities delegated from the HRC

3.1.3 Functions of Research sub-Committees

 Approval of research proposals of MOH employees of concerned departments/sections and the provision of technical support.

- Supervising and monitoring of research activities in concerned departments/sections in Ministry of Health.
- Capacity building in research for employees in concerned departments/sections.

3.2 Bahrain Branch of the UK Cochrane Centre

3.2.1 Role of the Bahrain Branch of the UK Cochrane Centre

The prime focus of the Bahrain Branch will be the co-ordination, development and provision of training and support to Cochrane review authors in the Arabic speaking countries. Another significantly important role will be the translation of necessary administrative, support and scientific documents from and to Arabic, to ensure that they can be understood by target audiences. Additionally the branch will develop a resource for hand searching Arabic-language healthcare journals and seek to identify and distribute relevant studies to the wider Collaboration.

3.2.2 Core functions of the Bahrain Branch UK Cochrane Centre

The core functions of the centre include; training and support, hand searching, and translation.

3.2.3 Accessibility of the Cochrane Library

The branch will seek to promote accessibility to The Cochrane Library to healthcare professionals, consumers and others within the region through the application of resources available from The Cochrane Collaboration website.

4. Managing and Financing Research

Several International guidelines were adapted in order to be used for the submission of research protocols. These guidelines and forms are available for all researchers in the internal internet network (intranet) for the MOH.

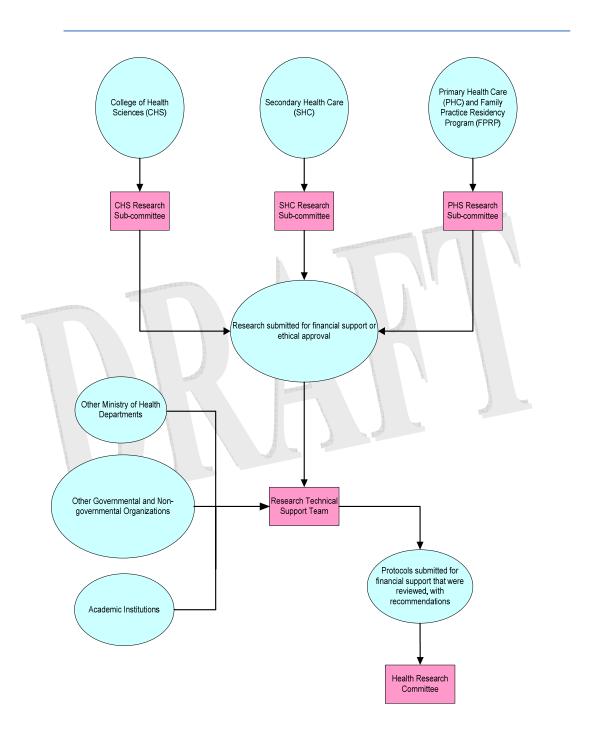
Financing research proposal was mainly through the MOH regular budget and funds allocated from several international agencies like WHO, GCC Council, UNDP, UNFPA etc. But with the new structure of Health research the committee submitted a separate budget within the general budget purely for funding research and was approved by Ministry of Finance for the year 2007-2008 budge

5. Submission of Research Protocols

5.1 Where should you submit your research protocol for approval?

- All research protocols from MOH staff should be directed to concerned Research Sub-committees (PHCRC, SHCRC and CHSRC).
- Researches that need further technical support, or ethical approval should be forwarded to the RTST by the sub-committees.
- Research that needs financial support should be forwarded to the RTST by the sub-committees. After assessing the priority and reliability of these studies recommendations will be raised to the main Health Research Committee.
- Research protocols from other departments/ sections of the ministry of health, academic institutions, and other governmental and nongovernmental organizations should be directed to RTST.

OUTLINE OF RESEARCH PROTOCOLS SUBMISSION



5.2 The Following Documents Should Be Submitted For Approval of Research Protocol

- A formal letter:
 - From the principal researcher (M.O.H staff).
 - PhD and Master Students should submit an official letter from the supervisor or administration in-charge.
 - Staff from other healthcare organizations should submit an official letter from the chief executive officer or chief of medical staff.
- Application for Approval of Research Proposal Form (Form 1) (PhD and Master students should submit full research protocol).
- Referee Data Sheet.
- Ethical Guidelines for Health Research Form for ethical approval (Form
 2).
- Budget Breakdown Table should be completed if research grant is required (found in the Application for Approval of Research Proposal Form).
 Note: all forms are also available on MOH web-site.

5.3 Where to Submit Your Research Protocol

You can submit your documents (soft or hard copies) to the following address:

Coordinator, Research and studies - MOH

Telephone; 17286051, 17286052, 17286054

Facsimile; 17286651

E-mail; hrcommittee@health.gov.bh

5.4 The following documents are useful guides

- Guidelines for Application for Health Research Approval.
- Ethical Guidelines for Health Research

5.5 Research Protocol Evaluation Feedback

You are going to receive Research Proposal Evaluation Form (Form 3) after the evaluation of your research protocol by the concerned committee.

Annex I

Health Research Committee

Chairman H.E. the Undersecretary The Assistant Undersecretary for Planning & Training Dep. Chairman Dean, College of Medicine & Medical Sciences / AGU Member Dean, College of Health Sciences Member Chairperson, SHC Research Sub-committee Member Chairperson, PHC Research Sub-committee Member Chairperson, CHS Research Sub-committee Member Members of Research Technical Support Team Members Epidemiologist and Biostatistician Member Rapporteur of Research Technical Support Team Rapporteur

Annex II

Research Technical Support Team

The Assistant Undersecretary for Planning & Training
Chief, Medical Review Office
Dep. Chairman
Prof. Randah Hamadeh - Epidemiologist, AUTP Advisor Member
Dr. Qassim Al Shboul - Biostatistician, AUTP Advisor
Dr. Ahmed Omran - Coordinator, H. Research & Studies
Rapporteur



Annex III

Secondary Health Care (SHC) Research Sum-committee

Dr. Fadheela Taher Al-Mahroos Chairperson Dep. Chairperson Dr. Ibtisam Al-Alawi Dr. Fadhel Abbas Al-Sabagh Member Dr. Nada Hasan Al-Yousif Member Dr. Ali Mirza Al-Qayim Member Dr. Jamila Mohamed Al-Salman Member Dr. Leena Mohamed Al-Qasimi Member Member Mrs. Fatima Isa Jaffar Mr. Shawqi Ali Skener Member Member Mrs. Huda Ali Ma'atooq



Annex IV

Primary Health Care (PHC) Research Sum-committee

Dr. Ibtisam Mohamed Fakhro

Dr. Khaldoon A.Razaq Al-Roomi

Dr. Mohamed Ali Mandil

Dr. Adel Salman Al-Sayyad

Dr. Raoof hamed Othman

Dr. Mariam Mohamed Al-Shitti

Chairperson

Dep. Chairman

Member

Member

Member



Annex V

College of Health Sciences (CHS) Research Sum-committee

Dr. Dr. Rajendra V. Awate. Chairman

Dr. Aysha A.Aziz Al-Sheikh Dep. Chairperson

Mr. Hasan Abdulla Al-Basri Member Mrs. Rakhsana Kawther Mohamed Member Mrs. Muneera Isa Al-Sawad Member Mrs. Muyasar Fadhli Awadhullah Member Mrs. Huda habib Jawad Member



Research Application Forms





Application for Approval of Research Proposal

Official Use only Date of receipt:		ID number:
Research Area:		
Referee 1:	Referee 2:	
Committee Approval: Yes	□ No	Date:
1. Name of the Principal Investigator a	nd institutional af	filiation:
Full name		
Occupation		
Department		
Full postal address of the Principal Invest	tigator:	
Telephone (office):	Telephor	ne (mobile):
Fax: e-mail:		
2. Name and signature of other investig	gators:	
1. Full name:	e-mail:	
Tel(mobile):	Signature:	
2. Full name:	e-mail:	
Tel(mobile):	Signature:	
3. Full name:	e-mail:	
Tel(mobile):	Signature:	
4. Full name:	e-mail:	
Tel(mobile):	Signature:	
I confirm that I have read and understoo Research Committee. I also accept respo regulations related to research & patient of Principal Investigator Signature:	nsibility for any irr	
Department Chairperson name & sign	ature:	

Research Proposal Format

<u>Title of the project</u>: (the title should be comprehensive, covering the main study objective(s) and study area)

<u>Background</u>: (Literature review of previous studies on the subject; and justification of the study by stating the problem and its public health importance)

- 1. Statement of the problem
- 2. Significance of the problem
- 3. Objectives of the study:

General objective: (the purpose of the study and goal that you need to achieve)

Specific objectives: (details of the general objective)

<u>Materials and methods</u>: (the research methods that could best achieve the study objectives)

- **Study area/setting:** (describe the area or setting where the study will be conducted)
- Study subjects: (eligibility and exclusion criteria of the study subjects)
- **Study design:** (mention the type of study design eg crosssectional, case-control, intervention study, etc..)
- Sample size: (mention the input criteria for sample size estimation. This might need the expertise of an epidemiologist)
- Sampling technique: (mention the sampling technique that will be used in order to obtain a representative sample for your target population. This might need the expertise of an epidemiologist)

<u>Data Collection methods</u>, instruments used, measurements

(Describe the instruments to be used for data collection (questionnaire, observation recording form, etc..).

<u>Data management and analysis plan</u>: (Describe the overall plan and tests used for data analysis and the statistical package used)

<u>Implications of study results to population health and health system policy in</u>

<u>Bahrain</u> (Expected results and potential contribution of the project to the decision making related to health care and policy in Bahrain)

Bibliographic references mention at least 10 recent articles relevant to the study subject

and enumerated according to their order of appearance in the text. (Exception to this is when the subject is in a new field)

Ethical Consideration:

- **1. Informed consent form** (If needed, please attach extra documents)
- **2. Institutional ethical clearance**(the ethical clearance of the Ministry of Health Bahrain is required)
- **3. Other funding agency** (specify if your study funded by another funding agency other than MOH)
- **Research reports:** (The final report should be submitted in the form of scientific article).
- Mechanisms to ensure <u>implementation of research</u> results in the health policy of the Ministry of Health.
- Strategies to enhance the dissemination and utilization of results.

Budget	Bahraini Dinars		
Budget breakdown	Total Budget requested	Budget requested from MOH	Budget requested from other sources
1. Manpower*			
Total Manpower			
2. Services			
a. Laboratory			
b. Radiology			
c. Others (please specify)			
Total Services			
3. Supplies and Equipment			
Total supplies			
4. Others			
Patients Cost			
Training			
Others (please, specify and justify)			
Total Other			
GRAND TOTAL			

^{*} Funds allocated to the research team should not exceed 30% of the budget.



Ethical Approval Form

1. Conflict of Interest Declaration

It is an ethical rule that investigators should have no undisclosed conflict of interest with their study collaborators, sponsors or subjects. Conflicts can arise, for example, when a commercial or other sponsor may not wish research results detrimental to their corporate image / interest to be disclosed, especially when the investigator is being remunerated by the sponsor for the research in question; when research subjects are being rewarded for their participation in the research; or when an investigator has a vested interest in, or is an employee / shareholder / director in the sponsor's corporate entity.

Is there any conflict of interest?
If yes, please provide details.
2. Study Subjects
Source:
☐ Inpatients ☐ Outpatients ☐ Volunteers ☐ Animals:
Age (humans):
☐ Neonates (<28 days) ☐ Infants (1-11 m) ☐ Children (1-12 yr)
Adolescent (13-17 yrs) Adults:
3 Datails of interventions

Details of interventions

A. Does the study involve the use of a new medicinal product or medical device or the use of an existing product outside the terms of its product license?

\square Yes \square No	
If yes, please complete Annex A of the Application Form.	
B. Will any ionizing or radioactive substances or X-Rays be ac	lministered?
☐ Yes ☐ No	
If yes, please complete Annex B of the Application Form.	
C. Please list those procedures in the study to which subjects will indicating those, which will be part of normal care and those tha additional (e.g. taking more samples than would otherwise be nec	at will be
D. Is there any treatment that will be withheld as a result of tal	king part in the
project? Yes No	king part in the
E. Are there any potential hazards?	Io
If yes, please give details, and give the likelihood and details of promeet them, and arrangements to deal with adverse events.	ecautions taken to
F. Is this study likely to cause any discomfort or distress?	
☐ Yes ☐ No	
If yes, please give details	and justify
G. Will information be given to the patient's doctor?	
☐ Yes ☐ No	
Please note: permission should always be sought from research subthis.	bjects before doing
If yes, please enclose an information sheet/letter for the patient's of justify:	doctor If no, please

		nvolved in this res	atients, will consent of all of earch be sought?	consultants whose
Į	<i>If</i>	no,	please	justify:
I. Us	e of Laborat	ory tests] Yes	\square No
Appr	roval of the d	lepartment of Path	nology Chairperson:	
J. I	ls <i>written</i> con	sent to be obtained	d? (see annex C) \(\subseteq Yes	\square No
	f yes, please	attach a copy of the	consent form to be used.	
Nam	e	of	Principal	Investigator
Signo	e d		Date	
Offic	ee Use only Approv	ed· Nota	approved:	
		f not approved:	аррго чеса.	
	Name:	on, Research Ethics	Committee	
	Signed:		Date:	

Annex A	Drugs and Devices

This form is to be used if the study involves the use of a new medical product or medical device (approved in country of origin) or the use of an existing product outside the terms of its produce license.

i)	Is a pharmaceut	ical or other commerc	ial company arr	anging this trial?
	If no, has approve	al of the licensing autho	prity in the MOH	been obtained?
ii)	Does the drug(s) which it is to be u	<u>-</u>	oduct license(s)	for the purpose for
	If yes, please atta	ch data sheet or equiva	lent.	
iii)		to be used (Please coll copies of this page as	- W	e below for each drug
	Approved Name	e(s):		
	Generic Name:			
	Trade Name:			
	Strength	Dosage & Frequency	Route	<u>Duration of Course</u>
iv)		not licensed for use in the following informa		peing used, applicants re than 2 A4 paper:
	a) What is the	e formulation, purity a	nd source of the	e Drug?
	b) What are th	he pharmacological ac	tions of the Dru	g - including those
	not			
	rolovant to	the proposed there were	tia indications?	
	reievant to	the proposed therapeu	uc muicauons:	

- c) Toxicology including details of species, number of animals, doses, duration of treatment and route(s) of administration. Important findings should be summarized.
- d) Clinical pharmacology in Man including:
 - Extent of Use in Man
 - Dosage schedules used dose, route, duration
 - Side effects and their frequency
 - Information on duration of action and mechanism of elimination, if known.
- e) Applicant's experience with this drug in man. Give brief information on previous studies, number and type of subjects and nature and incidence of side effects.

Details of Medical De	vice:			
If an electrical device	, has the device been t	hrough acce	ptance and safe	ety testing?
☐ Yes	□No			
Give details:				

Anı	nex B	Radiation
		m is to be used if the study involves the use of additional ionizing or ve substances or X-Rays.
a)	RAI	DIOACTIVE SUBSTANCES
	i) Do	etails of substances to be administered (Please complete the table below)
		Investigation:
		Radionuclide
		Chemical form
		Quantity of radio-activity to be administered Route Frequency (MBq)
甲	ii)	Estimated Effective Dose (Effective Dose Equivalent) (mSv): (Please supply source of reference or attach calculation)
b)	iii) X-R	Absorbed dose to organ or tissues concentrating radioactivity (mGy) (Specify dose and organ) (Please supply source of reference or attach calculation)
	i) ₁	Details of radiographic procedures
		<u>Investigation</u> <u>Organ(s)</u> <u>Frequency</u>
	ii)	Estimated Effective Dose (Effective Dose Equivalent) (mSv): (Please supply source of reference or attach calculation)
c)	Any c	contrast media will be used
d)	Any l	MRI will be used
e) A	Appro	oval from Department of Radiology Chairperson:
Anı	nex C	Standard Informed Consent

Standard informed consent should have the following elements:

- Researcher is identified and credentials presented
- Subject selection process is described
- Purpose of the study is described
- Study procedures are discussed
- Potential risks are described
- Potential benefits are described
- Compensation, if any, is discussed
- Alternative procedures, if any, are disclosed
- Anonymity or confidentiality is assured
- Right to refuse to participate or to withdraw from study without penalty is assured
- Offer to answer all questions is made
- Means of obtaining study results is presented



Referee Data Sheet
A NAME AND CONTACT DETAILS
Name
Mail Address
Phone
Mobile
Fax
Email 1
Email 2
Institution
B DISCIPLINE
Please list below one discipline which best describes your research expertise (Please choose from Appendix 1) 1
D FIELDS OF RESEARCH
Please list below, in order of priority, three fields of research 1 2 3
J J
E ADDITIONAL INFORMATION
Please briefly state your research interests. If you feel that the above fields do not fully reflect your areas of expertise please explain in the space below. Please specify any areas in which you <i>do not</i> wish to review applications on.
Please return this form to: Health Research Committee, PO Box 12, MOH, Bahrain. Telephone 17279879. Facsimile 17273540 Email: famin@health.gov.bh

Referee Participation Form

Name
Address
Phone
Fax
Email
As an expert referee for the Health Research Committee, MOH - Bahrain, I agree to the following regarding health research proposals forwarded by the Committee to me for review:
I will keep all matters pertaining to the content of the research proposal in strict confidence.
If necessary, I may seek the confidential opinion of a suitably qualified colleague for some aspects of a research proposal that may lie outside my field of expertise.
After reviewing the research proposal and forwarding that review to the Health Research Committee, I will destroy the research proposal and any materials related to my review of it.
Signed
Data

Please return this form to: Health Research Committee, PO Box 12, MOH, Bahrain. Telephone 17279879. Facsimile 17273540 Email: famin@health.gov.bh



Research Proposal Evaluation Form

Research title:			
Comments	Yes	N o	Not applicable
Title is comprehensive & covers the main study objective(s)			
Statement of the problem is clear			
Significance of the problem is mentioned			
Objectives and aims of the study are clear			
Materials and methods are adequately described			
eligibility and exclusion criteria of the study subjects are clear			
Study design is mentioned			
Sample size estimation is done			
The instruments to be used for data collection is described			
Data management and analysis plan is described			
Potential contribution of the project to the health care			
Bahrain is identified			
References are relevant and up-to-date			
Informed consent form is enclosed			
Ethically acceptable research			
	1	1	
Acceptable Research Proposal: Yes No			
(if no please give a brief explanation on the back of this Form)			
Acceptable with modification: Yes No			
Referee Name & signature:			
Date:			



Guidelines for Application for Health Research Approval

Researchers and health professionals working in the ministry of health should apply for MOH Research Committee approval before commencing research.

Objectives of Health Research Committee

- 1. Promote health system research in the Ministry of Health
- 2. Ensure research relevance to health care in Bahrain
- 3. Endorse utilization of research in health system policies & procedures and in decision making in the MOH
- 4. Ensure that patients will not be harmed by the research
- 5. Ensure scientific soundness and ethical integrity of the research

How to apply

- 1. The principal investigator should submit the duly completed Research Proposal Form 1 and Ethical Approval Form 2. Please follow the instructions mentioned next to each item in the format. An electronic version of the application Form is available at: http://intranet.health.gov.bh
- 2. Research Application Forms should be sent along with a covering letter to the vice Chairperson of the Health Research Committee. The researcher's department chairperson signature on the form is mandatory.
- 3. The researcher shall guarantee that he will stick to the protocol presented and major changes will require a written approval from the committee.
- 4. The researcher shall acknowledge the organization and all the people involved in his/her study.

- 5. If other departments (Radiology/Lab) are involved in the research and it entails extrawork load, the concerned department chairperson clearance is necessary.
- 6. The researcher must have the approval of the Research Committee for any research grant from any source outside the MOH.
- 7. The researcher should be aware that drug companies interested in combined research at MOH should send a letter to the Chairperson of the Research Committee, including the protocol of the research for written approval by MOH Research Committee.
- 8. Upon the approval from the committee, the Chairperson of the Health Research Committee shall send a letter to the principal investigator about the committee's decision.
- 9. The researcher should receive an answer for approval or request for further details about the committees decision in writing not later than three months from the time of the proposal receipt.

Research Funding

The Research Committee will fund some research proposals that requires funding and which meet the above-mentioned objectives and the eligibility criteria.

The following conditions are eligibility criteria for the selection of proposals for funding:

- 1. The researcher(s) should ensure scientific soundness of the proposal
- **2.** Ensure the potential of introduction of the research findings into policy and practice at the health sector in Bahrain.
- **3.** Ensure that it is related to and will focus on the identified research priorities and the 12 strategic goals of Bahrain Health Strategy of the MOH.

Exclusion criteria during the preliminary screening of the applications for funding.

- 4. Principal investigators with an ongoing funded project by the MOH-Bahrain. They are only eligible to apply for the grants after submission of their previous research final reports.
- 5. The proposal is the subject of a Master of PhD thesis for any member of the research team.

6. If another funding agency is sought to sponsor the research.

The regulation and procedures developed to protect the right of the patients and the MOH employee and to act as guideline for the researchers towards higher standard of research, thus it should be carefully reviewed by the applicant before signing the application form.

<u>Selection Process:</u> The selection committee will select applications based on the peer review of proposals. The criteria to be applied are scientific merit, relevance to the country priorities and implication to health care and health policies.





Ethical Guidelines for Health Research

The primary aim of medical/clinical research is to generate and refine knowledge without compromising patient care or harming the patient. In an attempt to achieve this aim, researchers at the MOH should take in consideration the ethical guidelines in the development and implementation of research studies.

Researchers shall focus on the protection of human subjects by observing the following principles:

- 1. Protecting the human rights & autonomy of study subjects through confidentiality and data protection.
- 2. Balancing benefits and risks of the study.
- 3. Securing informed consent.
- 4. Submitting the research proposal for institutional review.

Any clinical research project in the Ministry of Health by full time, part time staff and joint appointee from the Arabian Gulf University shall observe the following:

- 1. The proposed study should have a scientific merit.
- 2. No known risks to human subjects.
- 3. Patients must be thoroughly informed about the nature of the research.
- 4. Written consent (includes written description of all the possible risks involved) must be obtained from the patient.
- 5. The proposed clinical study has an impact and is significant to the profession.
- 6. The proposed clinical research had a written acceptance and ethical approval from the Ministry of Health Medical Research committee.
- 7. Financial supports from sources other than MOH must have a written permission from the MOH Health Research Committee.



Research Technical Sunpport Team 2008

