MAP Ministry of Health Ministerial-Wide Administrative Policy

1) ACCOUNTABILITY:

Number	MAP/MMRO/16/0002	**Version**	1.0
Title	**Regulation of Health Research in Human Subjects**		
Distribution Date	18th June 2016		
Effective Date	18th June 2020		
Revision Dates	**Last** 18th June 2016	**Target**	18th June 2020
Process Owner	Undersecretary of Ministry of Health		
Signatory Authority	H.E. the Minister of Health		
Location	Health Policy Network (HPN)		
Applicable Functions	Ministry of Health (MOH)		

2) KEYWORDS: health research committees, human subject research, ethics review, research approval, health research funding, research capacity

3) STATEMENT OF PURPOSE: To define the manner in which regulation of health research in human subjects is managed in MOH effectively and efficiently.

4) SCOPE:

- Members of the Health Research Committee and its subordinate committees, namely, the Research and Technical Support Team, and peripheral committees (Primary Healthcare Research Committee and Secondary Healthcare Research Committee and all staff/students/others who are involved in health research in human subjects at any MOH facilities, to provide the most effective and efficient operation of the policy.
- The Types of Health Research Studies Governed by This MAP Include:
  - Research involving vulnerable persons,
  - Other research involving human subjects, and
  - Research that does not involve human subjects but has ethical considerations.

  These include research conducted or supported in collaboration with a non-Bahraini institution. This MAP currently does not apply to research involving animal subjects exclusively.

5) RELATED REFERENCES:

- Health Research Structure & Procedures (2013).
- MOH Guidance to Applicants for the Approval of Health Research Proposals (2016).
- Ministry of Health: Circular of establishment of the Health Research Committee, Ministerial order no.19, 2005.
- ICH Harmonized Tripartite Guideline for Good Clinical Practice, E6 (R1) (1996).
- Code of Federal Regulations; 45 CFR 46, Protection of Human Subjects, 2009.
- National Health Regulatory authority NHRA Guideline

6) DEFINITIONS:
   - **Research:** Research is defined as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge".
   - **Human Subjects:** A human subject is defined as "a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information".
   - **Intervention** includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes. Interaction includes communication between the investigator and the subject. This includes face-to-face, mail and phone interaction as well as any other mode of communication. Identifiable private information includes information about behavior that occurs in a context in which an individual can reasonable expect that no observation is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
   - **MOH Research Committees:** Include four committees in MOH: The Health Research Committee (HRC), Research Technical Support Team (RTST) and Peripheral Research Committees, namely, the Primary Healthcare Research Committee (PHCRC), the Secondary Healthcare/Salmaniya Research Committee (SHCRC).

7) POLICY: All staff involved in the conduct of health research in human subjects at any MOH facility is responsible should comply with the Regulation of Health Research in Human Subjects policy process and procedure. This policy does not affect any local or foreign laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

8) RESPONSIBILITIES:
   i. Signatory Authority (H.E. the Minister of Health): To authorize and sign off the MAP.
   ii. Process Owner (Undersecretary): To maintain the MAP, to direct staff and to set policy.
   iii. Chief, Medical Review Office (MRO): To monitor and evaluate the implementation of the MAP.
   iv. Research committees and staff from MOH institutions and healthcare facilities engaged in health research: To implement the MAP.
   v. Health Research Committee (HRC): To regulate and advise the Ministry of Health on all aspects of health research in human subjects. The HRC will be the principal body for supporting, providing advice, setting standards of ethical behavior and regulating the conduct of health research in the ministry of health. The main functions of the HRC:
      a) To adopt health research policies, strategies and priorities in the MOH.
      b) To monitor health related research and to ensure its adherence to medical ethics.
      c) To build Research capacity for the MOH employees

d) To Document and disseminate research results
e) To approve research budget and grants
f) To cooperate with local, regional and international organizations

vi. The Research Technical Support Team (RTST): To ensure the protection of the rights, safety and well-being of human subjects involved in a research and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favorable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the research subjects.

The functions of the RTST are:

a) To technical support to research sub-committees
b) To approve research proposals of MOH employees and to provide technical support.
c) To approve research proposals submitted from other organizations and academic institutions intending to use MOH data or facilities.
d) To provide 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, information, or facilities and services
e) To build ministerial capacity in the field of health research
f) To coordinate with the HRC for identification of ministry's research needs and priorities
g) To Advice HRC regarding requests for Research Grants or Financial support
h) Other responsibilities delegated from the HRC

vii. Peripheral research committees: The functions of the peripheral research committees are:

a) To approve research proposals of MOH employees of concerned departments/sections and to provide technical support
b) To Supervise and to monitor research activities in concerned departments/sections in Ministry of Health
c) To build capacity in research for employees in concerned departments/sections

viii. Research Coordinator: To conduct preliminary screening of research proposal documents and ensure their completeness before their review by the research committees.

9) PROCEDURE FOR IMPLEMENTATION:

9.1. Approval of Research Proposals:

9.1.1. Clinical trials should be first authorized by NHRA then to apply to HRC for authorization

9.1.2. All activities involving “health research” and “human subjects”, including survey projects, conducted within any MOH facility must be subjected to review and official approval from the MOH research committees.

9.1.3. The Health Research Committee acknowledges that student/staff researchers may gain prior approval from their respective

institutional research review committees. However, final official approval must be sought from an MOH research committee in order to begin research. These cases should be subjected to an expedited review and can be processed swiftly.

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9.1.4. Researchers approaching the MOH research committees for approval must be informed and asked to comply with the procedures for research review and approval, as outlined in the "MOH Guidance to Applicants for the Approval of Health Research Proposals (2016).

9.1.5. The '*applicant'* for review and approval of a research project must be the Principal Investigator of the study (a student/ staff who is professionally based in Bahrain).

9.1.6. The **MOH Online Research Application System** is accessible via the MOH intranet and internet websites

9.1.7. Research approval applications will be initially handled by the Research coordinator, who will perform a preliminary screening of all documents provided, and request the researcher for any missing documents. Once the submission package is complete, the Research coordinator will assign a reference number and circulate the package to the committee members for review.

9.1.8. The outcome of review may be approval, conditional approval, re-submission or rejection of the research, depending on the nature of the findings. Researchers are entitled to appeal an unfavorable decision; this request, however, has to be approved by the RTST.

9.1.9. The MOH research committees *WILL NOT ISSUE* "retrospective ethics approval" for projects that could, and therefore should, have been reviewed through the normal review process.

9.2. Use of Patient Medical Records, Pathology and Radiology Services for Research:

9.2.1. Departments of healthcare facilities must request researchers for the MOH research approval letter before providing access to data, equipment or providing staff support. Support must be documented by means of a no-objection letter by the head of the concerned department.

9.2.2. Researcher access to patient medical records and biological samples require stringent monitoring. Medical record departments and pathology laboratories cannot authorize the use of medical records or biological samples without approval from an MOH research committee and the head of the respective department.

9.2.3. In addition, patients must be informed and consent to the use of their case records or samples in the form of a separate written consent form, wherever possible. Unauthorized use of patient private identifiable information must be strictly penalized.

9.3. Funding of Health Research:

9.3.1. The HRC will approve requests for technical support in the form of staff overtime, supply of equipment and bearing of indirect costs, based on the eligibility criteria detailed in the "*Guidance to Applicants for the Approval of Health Research*".

9.4. National Research Capacity Building:

9.4.1. The MRO will support the HRC in the area of health research capacity building by collaborating with stakeholders in the development of a national health research strategy and national research priorities.

9.4.2. The MRO will construct basic research courses that will guide potential researchers on research study designs, effective protocol writing and publication of results.

9.4.3. The MRO will track completed and ongoing research projects within the Kingdom of Bahrain by means of a health research registry.

10) TRAINING: Research Committees; all staff/students/others who are involved in health research in human subjects within facilities under the authority of the Ministry of Health, Bahrain must be trained to the level stated in their Job Description provided by the Civil Services Bureau as per their designated position provided with the associated Organizational Chart. Staff will undergo additional training as changes in services or technology dictate. Specific training requirements will be documented in the specific work area policy.

11) ACCESSIBILITY AND DISSEMINATION: All procedure manuals will have a specified location as per the accountability section, as well as on the intranet based Health Policy Network. The Process Owner will ensure that new/revised policies are disseminated and the manual is updated to reflect changes.

12) REVIEW: The Process Owner according to the review date in the accountability section will review the DPP/MAP. Medical Review Office will be responsible for initiating this review and will provide an updated review plan. Individual revisions of DPP/MAPs will be distributed to all areas of the MOH as authorized and should be inserted in the appropriate location of the policy manual.

13) REVISION: Revisions are made by preparing a new draft. Following final approval from SA, this revised DPP/MAP will then supersede the existing DPP/MAP. The format and approval procedures listed above will apply to the revised DPP/MAP.

14) AUTHORIZATION: All new or revised DPP/MAPs affecting the MOH will follow the above procedures and final approval for any modifications of a new DPP/MAP will rest solely with the SA.