Research at HMC:

A Guide for Staff

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HEALTH • EDUCATION • RESEARCH صحة • تعليم • بحوث

Introduction

Most advances in health and healthcare have resulted from research. Research can provide important information about how best to promote health and prevent disease. Research has also led to significant discoveries such as the development of new diagnostic tests and treatments, and has provided the evidence base as to which treatment is best. In addition, research can show us how care should be best organized, how to maximize quality of life and the best way we can care for and support our staff.

Hamad Medical Corporation (HMC) is dedicated to providing the safest, most effective and compassionate care to our patients and service users. An Academic Health System (AHS) is a healthcare system where clinical care, education and research are seamlessly integrated, and HMC is a senior partner in the Academic Health System of Qatar.

As healthcare professionals working in an AHS, we all have a responsibility to support research, to ensure the health, safety and well-being of research subjects and to facilitate access to research by patients and the public. Research in HMC is undertaken across all specialisms and facilities. It may include partnership with educational and healthcare providers across Qatar, as well as with international collaborators.

This leaflet is designed to help you answer general questions about research at HMC and to enable you to respond appropriately to queries posed by patients, their relatives, the public or other staff. It is intended to compliment research-awareness raising leaflets, which have been developed for patients and the public.

It will also help you understand how research is approved and governed at HMC and what approvals are necessary before research can begin.

It should also help you understand the steps you should take if you wish to undertake research.

The following are the important things you need to know.

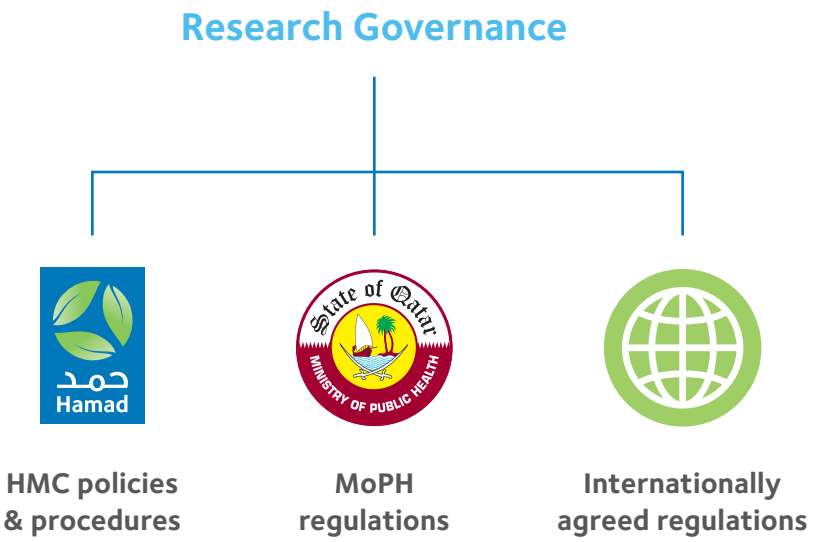
What is research?

Health research aims to inform and lead to improved practice by addressing clearly defined questions using systematic and rigorous methods.

How is research governed within HMC?

At HMC, research governance uses a framework of processes, policies and practices to review, approve and monitor research studies, as well as any relevant changes in the study.

These include ensuring any research adheres to HMC policies and procedures, Ministry of Public Health Regulations and internationally agreed regulations for research.



Oversight of research at HMC is provided by the study's Principal Investigator, each facility involved in the study, the Medical Research Center (MRC) and the Institutional Review Board (IRB):

- The MRC is responsible for the Corporate governance of all research, including the pre-approval and post-approval stages of the studies. This includes financial, legal and contractual requirements.
- IRB is responsible for the ethical oversight of research.
- The Principal Investigator (PI) is an appropriately trained and experienced researcher, responsible for the day-to-day management and overall conduct of research.
- Each facility involved is responsible for assessing and confirming the capacity and capability of the facility to conduct the research study. It also provides safety for human research subjects.

Before the start of a research study, the MRC and IRB ensure that appropriate checks and approvals are in place through a stringent review process.

No Human Subject Research can proceed without review and approval to ensure that all research studies comply with the legal and other regulatory requirements, including a review of the informed consent process and supporting information materials.

What is informed consent within the context of research?

Informed consent is an integral part of all clinical practice. Within the context of research, it describes the process during which the participant being recruited into a research project will learn about the study in a way they can understand and that enables them to make a meaningful decision as to whether to participate or not.

Critically, they should understand that they are free to decline to participate without it affecting their care in any way and that they may also withdraw at any time.

Generally, the research informed consent process will involve providing information which will include:

- the purpose of the research
- an outline of what will happen during the research
- what risks are involved
- what benefits may occur
- how information will be kept confidential
- the fact that participation in research is voluntary
- the fact that they may decline to participate without it affecting their care in any way
- the fact that they may withdraw at any time from the research without it affecting their care in any way
- whom to contact with questions

Informed consent process in research

If the patient decides to participate in a research study, the researcher will obtain consent according to the approved consent process outlined in the research application and protocol.

Participant consent is legally valid and professionally acceptable only if they have the capacity to decide whether to take part in the research, have been properly informed, and have agreed to participate without pressure or coercion.

If it ever appears that the patient is not clear that they are in a research study, what it entails or appears to have any doubts about participating, you must not continue with their participation and inform the treating clinician and person in charge of your concerns or seek advice from a senior member of staff.

It is important to understand that participants in research may be patients, relatives of patients, staff and members of the public.

What is my role in supporting and facilitating research?

All patient-facing staff in an academic health system have a responsibility to support research. This is different from undertaking or participating in research. You should be aware that research studies must have appropriate approvals in place and that patients must give informed consent before any research begins.

You should be aware that participants have the right to agree and decline to participate in research and withdraw from it without it affecting their care in any way.

You should know that the PI needs to be informed if a participant is involved in an adverse incident and that the incident is reported to the hospital risk management via HMC's electronic incident reporting system (RL solutions) as per the Occurrence, Variance and Accident (OVA) policy.

You should be able to respond to general enquires about research from patients, visitors, other staff members and the public.

You should know that if you have any concerns or you are unsure what to do, you can check with your line manager, the treating clinician or the person in charge. You can always get advice and guidance from the Medical Research Center.

What do I do if a patient or a visitor asks for information about research?

You are not expected to know about all the research undertaken at HMC or be able to answer questions about specific research projects. You are required to have only general knowledge about research and its governance and know where to direct queries, so that they are taken seriously and addressed. Additionally, it is important to know that research projects will have strict inclusion and exclusion criteria, so not all patients will be eligible for every research project.

Patients asking about research, in general, may be given a research leaflet. Those asking about specific research should be directed towards their treating clinician to speak to them about research, including research activity that they may be able to participate in.

If visitors or members of the public enquire about research at HMC, you may provide them with the leaflet entitled 'Research at HMC: General Information'.

What if my colleagues have a query about research?

If you are approached by a colleague with a query about research, you can explain you know that there are processes that need to be followed and approvals to be sought before any research can take place.

You should suggest that they complete HMC's approved training e-learning modules such as the Human Subject Research Module and the Collaborative Institutional Training Initiative (CITI).

You can signpost them to sources such as sharing this leaflet or suggest they seek help from their line manager and the MRC.

What should I know about myself or other staff as research subjects at HMC?

You should know that your role in supporting research is different from being a subject in a research project. Participating in research as a subject is not mandatory; you have the same entitlement as patients to actively participate or decline to take part in a study as a subject, without explanation and without it affecting your role or employment in any way.

If you or a colleague feels pressurized or coerced, talk with your line manager or other appropriate senior staff. You can also seek advice from the MRC.

Where can I get more information about research at HMC?

- **Human Subjects Research** eLearning course on the HITC eLearning Portal, under **Academic Research Program** (http://hamad.qa/elearning)

- More information about **Human Subject Research** is available through the Collaborative Institutional Training Initiative (CITI) program homepage. You can go there and select the categories which are pertinent to your role or interests.

- **The MRC** also provides onsite training throughout the year. For further information about research or the onsite training, you can contact MRC via MRChelpdesk@hamad.qa, or use the MRC Intranet to find out what educational activities are occurring.

- For policies about **Human Subject Research**, please refer to the Human Subjects Research Programs Policies on the Corporate policy intranet.