GOVERNMENT OF DUBAI

سلطة مدينة دبي الطبية
Dubai Healthcare City Authority
Regulatory - القطاع التنظيمي

Dubai Healthcare City Authority – Regulatory

Quick Reference Guide

Research in Dubai Healthcare City

Understanding Requirements, Processes and Procedures

DHCR reserves the right to amend this guideline from time to time.
The latest version of the document shall be made readily available to interested parties.

Foreword

The information in this document is intended for members of the Dubai Healthcare City (DHCC) research community including but not limited to healthcare professionals, investigators, administrators, council and committee members. It is a guidance document and should be implemented in conjunction with professional knowledge skills and experience.

All members of the DHCC community who engage or wish to participate in research involving human subjects, use of human tissue or personal health information must be knowledgeable about the Dubai Healthcare City Authority – Regulation Standards, Policies and Procedures concerning research and the subject matters that they are concerned.

Introduction

The mission of the Dubai Healthcare City Authority-Regulation (DHCR) is to protect the rights and welfare of human subjects participating in research conducted within Dubai Healthcare City.

Consistent with its mission, the objectives of DHCR is to set out the framework for regulatory compliance, promoting principles of good practice and issuing guidance which ensure that human subject research is conducted with appropriate professional expertise and according to the highest ethical and scientific standards.

This document is intended as a quick reference guide to describe the requirements and procedures for Final Protocols, Protocol Amendments and other documentation in research studies conducted in DHCC.

- **Part One: Details the requirements when starting up a new research study**
- **Part Two: Details the requirements after receiving approval**

PART ONE: Setting up your research study

Research in DHCC

All research, including clinical or non-clinical involving patients, service users, healthcare professionals or volunteers, (including their tissue and data), within DHCC is subject to strict regulatory adherence to the framework set by DHCR.

DHCR defines research as *the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.*

Different types of research carry different risks. While all research requires written approval from DHCR, the requirements for ethical review differ depending on the type of study.

When setting up a study, it is important to understand what category the proposed research falls under and to establish whether the proposed research is permissible within DHCC.

Researchers and/or the host organisation are obligated to ensure all required approvals are in place before initiating any research.

Research regulation and ethical principles that guide DHCR are derived from the following:

- Federal Laws of the UAE
- Research Regulation No. (6) of 2013
- World Medical Association Declaration of Helsinki: *Ethical Principles for Medical Research Involving Human Subjects*
- International Conference on Harmonization Good Clinical Practice.

What approvals are needed to conduct a research study?

DHCR mandates the following three approvals need to be in place before initiating a study in DHCC:

1. Research Permit approval for the organisation (see Research Permit Guidance for Operators)

2. Research Ethics Review Committee (RERC) approval for an individual research study

3. DHCR Research Governance approval for the organisation to conduct the individual research study

To ensure efficient start-up of research within the community, all three approvals may be sought simultaneously

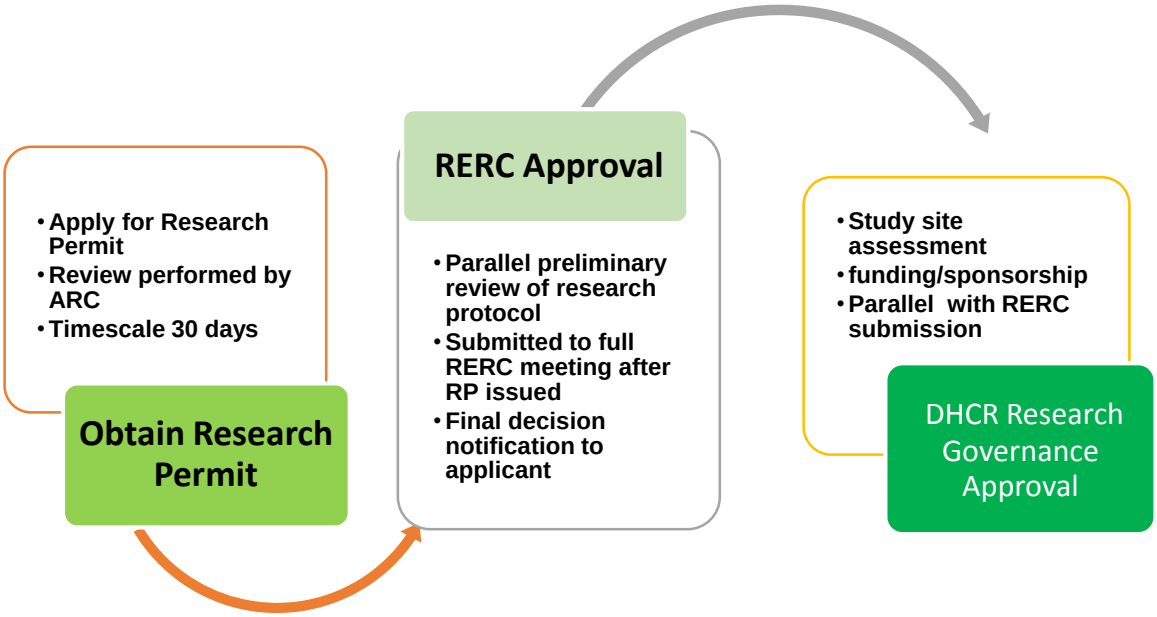

Figure 1: Overview of regulatory approvals needed to conduct research in DHCC

Research Permit approval

Research may only be undertaken by an approved Research Permit Operator within DHCC. Obtaining a Research Permit is the **First stage** which may lead to the subsequent submission of an individual research project for ethical and governance review and approval respectively. For further information, see Research Regulation No. (6) and DHCR Research Permit Guidance for Operators. The summary process is described below in figure 2.

What documents do I need to submit?

This information is included in the DHCR Research Permit Guidance Operators.

Fees

There are different fees based on the type of research activity proposed in the request for a permit and can be determined from the current DHCR pricelist.

* If guidance is needed the applicant may schedule a pre-submission meeting whereby the A & R team will help prepare the package.

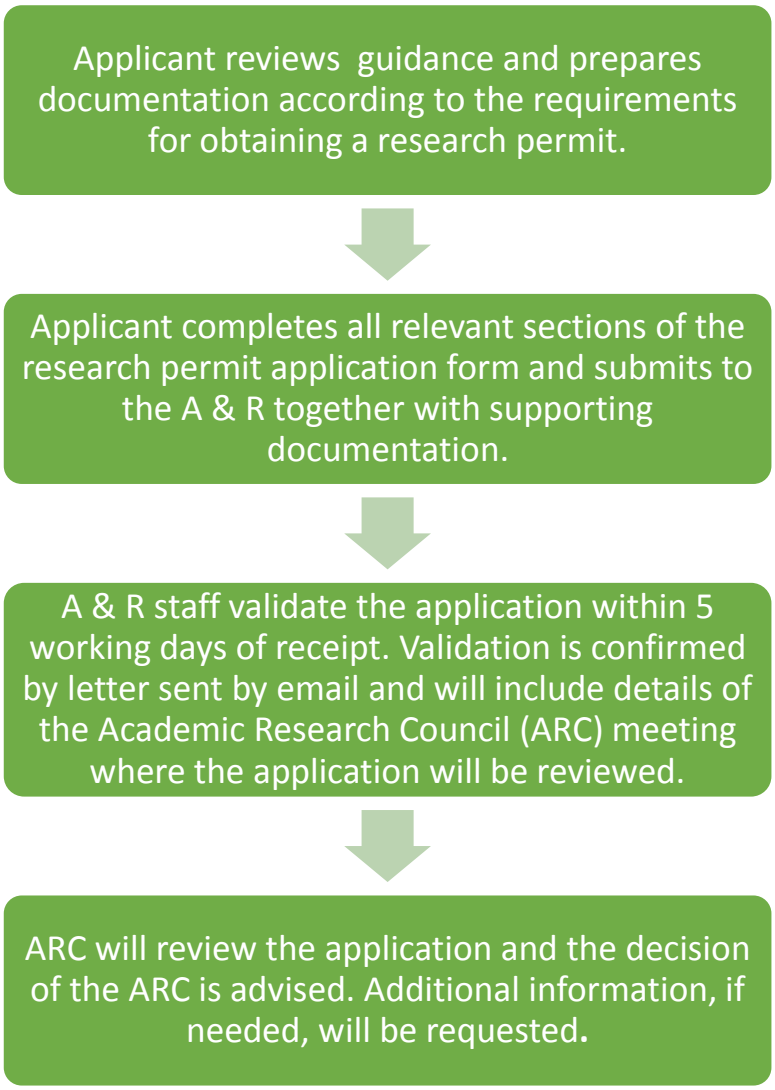

Figure 2: Summary process for obtaining a new Research Permit

Research Ethics Review Committee approval

DHCR has empowered the RERC to review and provide an ethical opinion on any research protocol/study involving:

- Patients and service users of facilities established in DHCC.
- Access to data, organs or other bodily material of past or present DHCC patients
- The use of, or potential access to, DHCC premises or facilities
- Individuals working as staff at any DHCC operator recruited as research participants by their professional role.

Additional regulatory measures are required for any research which involves:
a) Fetal material and IVF involving DHCC patients
b) The recently deceased at DHCC premises

Prior authorization from the Academic and Research Council, DHCR is required before submission to the RERC.

Where do I apply for an ethical review?

An application for ethical review must be made in writing to the RERC. The RERC will consider the application at a meeting which will usually take place on a monthly basis to ensure that decisions can be made within 60 calendar days.

What documents do I need to submit for ethical review?

The RERC will undertake review to safeguard the rights, safety, and well-being of research subjects. As such they must review all documents and information to decide whether the proposed research is ethical. While the complete list of documents will vary depending on the type of research study, standard requirements are provided in *Research Permit Guidance for Operators*, however further documents may be required subject to the requests of the RERC.

How do I apply for RERC approval?

All new applications must be made using the initial protocol application form, which is available from www.dhcc.ae

Applicants should review relevant guidance documents before completing the application and prepare documents. If further guidance or any clarification is needed, a pre-submission meeting may be scheduled whereby the Academic and Research Office (A and R) staff will help support preparation of the submission package.

When all documents are complete, the applicant should contact the A and R office to submit. Five paper copies of the application form, with all relevant signatures in ink, should be sent together with all supporting documents.

A and R staff will validate the application within ten working days of receipt. Validation will be confirmed by letter sent by email and will include details of the RERC meeting.

The applicant may be requested to attend the RERC meeting, if required details will be included in the validation letter.

The RERC will review the application and the decision of the RERC will be advised.

Applicants will be notified of the decision within 10 working days of the RERC meeting at which their application was reviewed.

RERC decisions and possible outcomes

Decisions of the RERC may include:

- ***Provisional Opinion***
- The RERC may decide to seek clarification on specific issues before the decision is made. The applicant may be required to submit further information as requested if RERC or the A and R department consider the application is incomplete.

- ***Unfavorable Opinion***
- If the response received is not satisfactory then the committee may give an unfavourable opinion. Applicants will be requested to modify and resubmit application.

- ***Favorable Opinion***
- RERC approves the research and will specify the terms and conditions of approval in the notification letter.

Fees

Fees for ethical review are applicable. There are different fees based on the type of research study and can be determined from the current DHCR pricelist.

DHCR Research Governance Approval

DHCR Research Governance brings together the assessment of governance and legal compliance. It ensures that research conducted within DHCC meet the required high scientific and ethical standards but also reviews the allocation of responsibilities within the research team confirming their capacty to deliver the study.

How do I apply for a DHCR Research Governance approval and what documents do I need to submit?

The research governance review consists of an evaluation of a research operator to the research proposal submitted. There are no formal meetings for research governance approval, however the process is ongoing. The process begins when an application is received for ethical review and ends with final approval once all governance criteria have been met.

The documents required for review are those that will usually be part of the research permit and ethical review package. Additional documents will include the proposed study contract and study budget. Applicants will be advised of any further documents if required.

Process of review and timeframe for approval

The governance criteria to be satisfied includes an evaluation of the proposed study site to the requirements of the research protocol. In addition, final approval is dependent on a valid Research Permit being in place and a favorable ethical opinion. Applicants will usually be notified within five working days of receiving the approval from the ethics committee.

PART TWO: During your research study

After approval

Once your research has been approved you will need to keep DHCR Research Governance and the RERC updated on any issues that arise during the conduct of your study such as amendments, progress reports, safety information reporting.

Amendments

Amendments are changes made to the research after a favourable ethical opinion has been granted. Amendments can be either substantial or minor.

- ***Substantial amendments***
  Substantial amendments are all amendments that are not administrative and need the prior approval from the RERC.
  All substantial amendments must be submitted on the relevant form which is available from www.dhcc.ae . The RERC will give an opinion on a substantial amendment within 35 days. If the substantial amendment is given an unfavourable opinion the applicant may submit a modified amendment, which will be reviewed within a further 14 days. Substantial amendments can only be implemented once the RERC has provided approval.
- ***Non-substantial amendments***
  Non substantial or minor amendments are purely administrative details that do not need full review. They can be submitted to DHCR and the RERC for notification and will be acknowledged once advised.

What types of amendments are considered substantial and non - substantial?

Substantial Amendments	Non substantial amendments
Changes to the design or methodology of the study, or to background information affecting scientific value.	Correction of typographical errors in the protocol or other study documentation.
Changes to the procedures undertaken by research participants.	Other minor clarifications of the protocol.
Any change relating to the safety or physical/mental integrity of subjects, or to the risk/benefit analysis for the study	Changes to the PI's research team (other than appointment of key collaborators).
Changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, information sheets for relatives or carers.	Changes to the research team at particular trial sites (other than appointment of a new PI).
A change of sponsor(s)	Changes in documentation used by the research team for recording study data.
Appointment of a new PI (Principal Investigator) or key collaborator, or temporary arrangements to cover the absence of a PI	
Change to the insurance or indemnity arrangements for the study.	
Inclusion of a new research site (not listed in the original application) in a study	
Appointment of a new PI at a research site	
Changes in funding arrangements	
Change to the definition of the end of the study	

Safety Information Reporting

Urgent Safety Measures

The sponsor or investigator may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety, without prior authorisation from DHCR.

However, a notification must be immediately submitted, in any event within three days, in the form of a substantial amendment, that such measures have been taken and the reasons why.

Safety reporting to the DHCR and RERC

For clinical trials of investigational medicinal products copies of all safety information, including Annual Safety Update Reports supplied to DHCR must be sent to the RERC.
For all other studies, including clinical investigations of medical devices, only reports of related and unexpected Serious Adverse Events (SAEs) should be submitted to the RERC.

These should be sent within 15 days of the principal investigator becoming aware of the event. Reports of related and unexpected SAEs in double-blind trials should be unblinded.

Safety reporting for SUSARs

Any significant findings and recommendations of an independent data monitoring committee or equivalent body established for the trial should be reported to DHCR and the RERC.

Expedited reports of Suspected Unexpected Serious Adverse Reactions (SUSARs) and annual Safety Update Reports must be submitted routinely.

The definition of SUSARs are as set out in the ICH GCP guidelines.

A SUSAR which is fatal or life-threatening should be reported as soon as possible and in any event within seven days after the sponsor became aware of the event.

Any additional information must be reported within eight days of sending the first report. This includes SUSARs associated with active comparator drugs. Reports of SUSARs in double-blind trials should be unblinded.

Annual Safety Update Reports should concisely describe all new safety information relevant for one or several clinical trial(s) and assess the safety of subjects included in these studies.

Safety reporting for clinical investigations of medical devices

All serious adverse events, whether initially considered to be device related or not, involving a device under clinical investigation should be reported immediately to DHCR. This includes events occurring outside the DHCC, where the investigation is also being conducted in the UAE.

Progress Reports

A progress report should be submitted to the RERC 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted thereafter until the end of the study. There are separate forms for submitting progress reports depending on the type of research. For clinical trials of investigational medicinal products (CTIMPs) or medical devices this progress report is in addition to the annual safety report.

DHCR Research Governance

Applicants should make regular progress reports to the DHCR Research Governance.
DHCR will generally accept a copy of the annual progress report that has been submitted to the RERC. Individual sites may also be required to report on initiation, recruitment and completion to the A and R department and may be subject to audit and inspection in accordance with DHCR regulations and policies.

Early termination or temporary halt of study

If the study is terminated early or is temporarily suspended, applicants should notify all relevant review bodies within 15 days.

Preparing for the end of the study

The definition of the end of the study should be within the protocol and any change to this definition after approval has been given for the research should be notified to the appropriate review body(ies) as a substantial amendment. In most cases, this will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol.

At the end of a study applicants will normally need to declare the end of the study using the appropriate form(s) and provide a final report to the appropriate body (ies) within defined timelines.

Before completing the declaration of the end of the study, a review should be performed to assess whether the plans as approved by the RERC for use of tissue and data collected in the course of the study, providing information to participants, and dissemination of results were completed. If there are any changes anticipated to these approved arrangements, applicants should consider whether a substantial amendment is required.

On receipt of an End of Study Declaration, the RERC will issue an acknowledgement of receipt, requesting any further information if required.

Further reading and resources

- Research Regulation No. (6) of 2013
- World Medical Association Declaration of Helsinki: *Ethical Principles for Medical Research Involving Human Subjects*
- International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice ('ICH GCP') 1996. Available: http://www.ich.org/LOB/media/MEDIA482.pdf [Accessed 22 June 2016]. Reference Type: Electronic Citation

Contact

Further advice on the application of this guidance may be sought from Academic and Research Department, DHCR on +9714 3838300 (Sunday to Thursday 8.30am – 4.30pm)
Email: research@dhcr.gov.ae