GOVERNMENT OF DUBAI

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

Dubai Healthcare City Authority – Regulatory

Research in Dubai Healthcare City

Research Permit Guide for Operators

The Requirements, Processes and Procedures

DHCC Research Permit Guide V2
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Introduction

The vision of Dubai Healthcare City is to achieve recognition as an international location of choice as an integrated centre of excellence for medical education and research.

Dubai Healthcare City Authority - Regulation (DHCR) is the independent regulatory body responsible for promoting research excellence through licensing and monitoring of all education service providers operating within DHCC free.

DHCR, in line with its commitment to promoting research and assuring high quality research activities, issued the Research Regulation No. (6) of 2013 in accordance with the Law, Federal Rules and Regulations to set out the framework under which research services may be carried out within DHCC.

This document will guide applicants to meet the regulatory requirements for compliance in relation to Research. Specifically, it describes the following:

Legal framework

- There is a legal obligation upon all Operators conducting or planning to conduct research within DHCC to be appropriately licensed.
- As stated in the Research Regulation No (6) '...no person or Entity may operate Research Programs within DHCC unless it is an Entity established within DHCC and has obtained and maintains a Research Permit in accordance with the Research Regulation and applicable Rules, Standards and Policies...'
- Failure to comply with the requirements of obtaining and maintaining a Research Permit will result in a breach of the research governance rules and regulations as issued by DHCR. Penalties or violations may be issued against any such Operator as deemed appropriate by the Clinical Affairs Department.

Defining Research

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

- All research, clinical or non-clinical that shall involve patients, service users, healthcare professionals or volunteers or their tissue or data, within DHCC is subject to strict adherence to the regulatory framework set by DHCR pertaining research.
- The DHCR document entitled Decision One (2016) lists the types of organisations that are recognised as requiring a Research Permit. This list is not exhaustive or exclusive but is intended to guide applicants in respect of those programs that guidance on the status of, as research services or otherwise, has previously been sought. DHCR will review and update this list periodically. (Refer to Table 1)

This document is intended to supplement DHCR's broader policy framework on research within DHCC and the DHCR Quick Reference Guide Research in Dubai Healthcare City.

Research Permit

- A valid Research Permit is a prerequisite requirement for any operator that will conduct research activity or services as part of their operations.

Facilities eligible to apply for a Research Permit

- Research activity or services may be standalone services or may be as part of the services offered by the operator.

Validity period for a Research Permit

- Once issued, the permit will be valid for two years and will require continued review and reassessment by way of applying for renewal of a research permit.

Adding new research programs or services to an issued Research Permit

- If an operator wishes to conduct research or provide research services that were not part of their initial (new) application for a Research Permit, an amendment request for a Research Permit will be necessary.

Application process for Research Permits

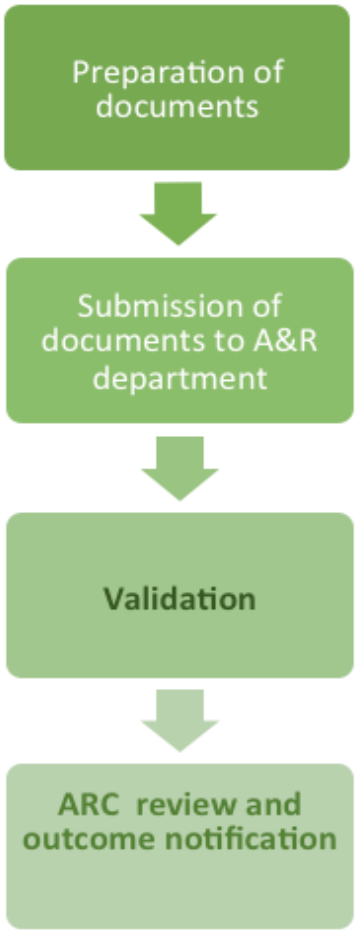
- Research Permit requests must be made in writing, electronically to the Academic and Research Department (ARD), DHCR and shall be made by the authorised person on behalf of the named operator.

- All new, renewal or amendment Research Permit requests are received and processed in the same way, the prerequisite requirements, application forms and supporting documents required for review vary. (refer to Figure 1)

- The review and assessment of all applications types will be performed by the Academic and Research Council (ARC) at a monthly meeting.

- Research permits are issued for the organisation where it is intended the research activity will take place.

Figure 1



Step 1
Applicant reviews relevant guidance and prepares documentation according to the requirements for obtaining a research permit.

Step 2
The relevant research permit application form together with supporting documents is submitted to the ARD. One hard copy and soft copy is required for submission.

Step 3
ARD staff will validate the application within five working days of receipt.

Step 4
ARC will review the application, and the decision of the ARC is advised. Additional information, if needed, will be requested.

- Only one completed application for a research permit shall be submitted per operator.

  However, the scope of research activities approved may include more than one type

Preparation of applications

Research permits are issued for the organisation where it is intended the research will take place. Consequently, the submission package will consist of those

- documents which relate to the policies and provisions in place for the research activity as proposed.

- The required documents for assessment will vary depending on the type of research activity intended. Standard requirements are provided in Table 1.
- It is recommended that the applicant schedule a pre-submission meeting with the Academic and Research department to discuss the scope of intended research activities so that the applicant can be guided to the correct application form and supporting documents required.
- Once the submission package is ready to submit, the applicant will contact the Academic and Research department to schedule review at the next ARC meeting once documents.
- One hard copy and a soft copy of all documents will be required. The Academic and Research division will advise the applicant on the format and number of hard copies required.
- Applicants will be advised for the cut off point for submission of all documents in time for review at the ARC meeting. Generally, the cut off point for receipt of documents is 20 days prior to the next planned ARC meeting.

Validation criteria

On receipt of documents, the application will be validated. An application will be accepted as valid if it meets the following criteria:

- Mandatory documents as per the relevant research permit checklist have been provided.
- The relevant application form has been correctly completed and submitted together with all supporting documents.
- All text is in English and the print is clearly legible.
- The application form has been signed and dated on behalf of the Operator.

Valid applications

If an application is valid, the Academic and Research department will notify the applicant by sending a validation letter by email which will include details of the ARC meeting at which the application will be reviewed.

It is not likely that attendance from an Operator will be requested at the ARC meeting, if however, it is considered necessary, the Academic and Research department will inform the Operator in the validation letter and will include relevant information about the local meeting procedures.

Invalid applications

If an application is considered invalid, the Academic and Research department will notify the Operator by sending an invalid application letter by email. The validation letter will include details of reasons for invalidation.

Only valid applications are accepted for review by the ARC.

Revisions to an application following submission

Changes to an application that has been validated and scheduled for review should not be accepted before the ARC meeting unless agreed and approved by the Academic and Research Manager.

Where an Operator considers it necessary to make significant changes to an application or any supporting documentation submitted as part of the research permit submission package before ARC review, the Operator will be advised to withdraw the application.

Minor changes are at the discretion of the Academic and Research Manager following consultation with the ARC Chair.

Where the ARC has granted provisional approval pending further information or clarification, the Operator may be authorised to highlight any further changes in the response letter submitted to the ARC. Such changes must be agreed by the Academic and Research Manager, prior to resubmission.

All changes to an application and supporting documentation must be clearly highlighted, where applicable a new version number and date should be given.

Withdrawal of applications

Where an Operator withdraws an application it will no longer be valid and will be documented as 'withdrawn by applicant'. The Operator must provide a clear reason for withdrawing the application, which will have recorded by the Academic and Research Manager and reported to the Registry of Companies.

Following withdrawal, if an Operator decides to resubmit the same application at a later date, the applicant should notify the Academic and Research department of the previous withdrawal.

Retrospective applications

DHCR does not accept any retrospective Research Permit applications.

Table 2: Key documents required for Research Permit applications

Document Type	New Research Permit	Renewal Research Permit	Amendment Research Permit
Completed, signed and dated Research Permit Application Form	✓	✓	✓
Completed New Research Permit Checklist	✓	✓	✓
Research Program (s) Details or Proposed Plan	✓	✓	✓
Evidence of the operator being equipped to conduct proposed research, to include policy documents			
Informed consent procedures	✓	✓	✓
Investigational medicinal product management procedures	✓	✓	✓
Medical records management procedures	✓	✓	✓
Data protection policy	✓	✓	✓
Evidence statement that personnel planned to be involved in research are qualified by research, training, experience for the proposed research; and have proof of GCP training	✓	✓	✓
Laboratory operating procedures, lab accreditation and certificates as applicable	✓	✓	✓
Other equipment policy documents, as applicable	✓	✓	✓

Timeframe for review and assessment

Research Permit requests will be processed within 30 days of the date as stated in the validation letter.

Expedited review is possible subject to discretion of the Academic and Research Department, fees will be payable for expedition.

Decisions by the ARC

Upon review of an application, members of the ARC shall vote to:

1. Approve the Application for a Research Permit;
2. Approve the Application for a Research Permit subject to conditions or restrictions as deemed necessary to be included in the Research Permit; or
3. Deny the Application for a Research Permit.

Notifications of the ARC decisions

The Operator will be notified of the ARC decision within 3 working days of the ARC meeting. Notifications will be sent by email to the responsible persons as listed on the initial application.

Approved application

If an Operator is approved, the Research Permit will be prepared in accordance with the details as specified by the Research Regulation.

- The approval notification will include terms of the Research Permit.
- The term of the initial permit shall generally be 2 years, expiring on the anniversary of its issue, unless otherwise stated.
- The dates for renewal will be advised
- Any special conditions will also be included such as progress reporting period, i.e. every 3 months, 6 months etc.

Conditional approval/ Request for clarification or further information

- Where the ARC has issued a provisional opinion and/or requested clarification or further information, the applicant will be requested to provide further details to allow a full and final decision to be made.

- The conditional approval notification letter will state what these conditions and clarifications or request for further information are and will also specify the cutoff date for submission of a response.
- In the event that an Operator fails to resubmit by the specified cutoff date, it is at the discretion of ARD (after deliberation with the ARC Chair) whether or not to accept the application.
- Applications that are not accepted will be required to resubmit a full initial application.

Denying a Permit

Where an Operator's request for a permit has been denied, the ARC will provide full reasons for denial.

An application may be denied if it is determined, based on credible evidence, that:

- any statements, information or documents submitted by the Operator are false, misleading or deceptive or are likely to mislead or deceive;
- there has been a modification or change in the circumstances relating to the information or documentation contained in the Application after its filing and the Operator has failed to notify the ARC of any such modification or change promptly;
- The Operator has failed to satisfy any of the requirements, and is considered to meet the requirements that the Operator shall comply with the provisions of the Research Regulation and the applicable Rules, Standards and Policies, if it were to hold a Research Permit.

Fees

Fees based on the type of research activity proposed in the Research permit request and can be determined from the current DHCR pricelist available at www.dhcc.ae

Applying for a new Research Permit

New Operators not yet established

- Where the operator is not yet established within DHCC, it must inform the Registry of Companies of their intended scope of services as early as possible, at the latest prior to being issued a Commercial License.
- Whilst early discussions with the Academic & Research department are encouraged, only on receipt of obtaining Provisional Approval from the Registry of Companies, may an operator formally submit an application for review by the ARC.

Renewal of a Research Permit

- Each Approved Research Operator is required to renew its Research Permit every 2 years, effective from the date of issuance of its initial Research Permit, unless otherwise specified at the time of granting initial approval.
- Each date on which an Approved Research Operator's Research Permit is to be renewed is the "Renewal Date".
- Where an Approved Research Operator fails to file a Renewal Application for its Research Permit in accordance with the requirements as stated in the Research Regulation, its Research Permit shall automatically terminate upon the expiry of its term or extended term.
- In such cases and the Approved Research Operator shall immediately cease providing any or all Research Programs under the Research Permit.

Documents to submit with a Renewal Application, Validation and Review process for a Renewal Application

- The process for submission and review of a renewal research permit application is the same as with a new research permit application, with the exception of the specified timeframe in which applications should reach the ARC.
- A completed Renewal Application package must be submitted no later than 60 days prior to each Renewal Date as specified in the initial approval or subsequent renewal approval.

- The ARD may, at its discretion, allow a Renewal Application to be filed later but any such extension shall be for no greater than 60 days. This must be in all cases approved in writing by the ARD ahead of the permit expiry.
- A renewal application package and prerequisites documents will vary depending on the type of Research activity or services the Operator proposes to renew.
- The Operator must review the relevant guidance documents and complete the Renewal Application form depending on the type of service (s) they intend to renew.

Amendment or modification request of a Research Permit

Any changes to an existing Research Permit would require modification of the permit and may require a new application to be submitted.

Contact

Further advice on the application of this guidance may be sought from Academic and Research Department, DHCR.

Telephone: +9714 3838300 (Sunday to Thursday 8.30am – 4.30pm)

Email: research@dhcr.gov.ae