CONDUCTING RESEARCH IN DUBAI HEALTHCARE CITY

Policy and Procedure

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Conducting Research in Dubai Healthcare City Policy and Procedure

INTRODUCTION

Research is essential for the advancement of medical knowledge, development of new treatments, and delivery of efficient services for the health and wellbeing of patients, service users, and the wider society**.** The vision of DHCC is to be the internationally recognized location of choice for quality healthcare services and an integrated center of excellence for clinical and wellness services, medical education, and research. Dubai Healthcare City Authority – Regulatory (DHCR) is responsible for regulating all aspects of research within the free zone and it is mandatory to have a valid research permit to conduct research within Dubai Healthcare City (DHCC).

The mission of the DHCR Research Department is to protect the rights of human subjects and welfare of animals involved in research conducted within DHCC as well as to guard the reputation of DHCC, Dubai, and the UAE**.** Supporting the DHCR Research Department in its role are the DHCR Academic and Research Council and the Research Ethics Committee.

The ultimate responsibility to comply with the approval of ethical standards rests with the Investigator(s) carrying out the research project, the associated Approved Research Operator and the Study Sponsor where applicable.

1- Purpose:

1.1	Set out a strong and transparent governance framework for regulatory compliance, promoting principles of good practice, and issuing guidance which ensure that research is conducted with appropriate professional expertise and according to the highest ethical and scientific standards.
1.2	Provide guidance to Entities and Approved Research Operators conducting or intending to conduct research activities in DHCC. It includes policies, procedures, guidelines, as well as the necessary forms for researchers to prepare, submit, and seek ethical approval for their research studies.

2- Scope of application:

2.1	Any and all research activities that may be carried out within DHCC.

3- Applicable To:

3.1	All DHCC Entities and Approved Research Operators conducting or intending to conduct research activities in DHCC.

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4- Policy:

4.1	DHCR is committed to maintaining the highest ethical and scientific standards in all aspects of research carried out in DHCC by providing a framework for good research conduct and its governance.
4.2	All DHCC Entities and Approved Research Operators and associated researchers conducting or intending to conduct research activities in DHCC must act in accordance with all relevant UAE laws, DHCR rules, policies, and guidelines; and should abide with the cultural norms within the UAE.
4.3	Any DHCC Entity intending to conduct research activities in DHCC must first apply for and obtain a Research Permit. The application is initially reviewed by the DHCR Research Department and then by the DHCR Academic and Research Council (ARC) who then issue the permit once all the Permit requirements are met. Upon obtaining a Research Permit, the Entity becomes an Approved Research Operator (ARO) within DHCC.
4.4	All Approved Research Operators are required to obtain approval for individual Research Proposals prior to commencing research activities within DHCC. Review of Research Proposals is carried out by the DHCR Research Ethics Committee (REC).
4.5	All AROs are required to submit a minimum of one (1) Research Proposal for review by the DHCR REC during the duration of their active Research Permit. AROs with an ongoing research study must submit a progress report summarizing the study's progress at the time of renewal of the Research Permit and as required by the REC.
4.6	AROs must begin the process of Research Permit renewal 60-30 days prior to the expiry date of the existing active Permit.
4.7	Prior to commencing the research activity, the ARO is responsible for obtaining all necessary approvals (such as ethics committee approvals) from within and outside of DHCC as applicable.
4.8	Research Proposals that have already obtained ethical approval from a recognized entity as defined by UAE Medical Liability Law No. 4 of 2016 is eligible for expedited review by DHCR.
4.9	A new Research Permit's expiry date will be aligned with that of the Entity's Commercial License with the relevant fees being prorated accordingly.
4.10	The Research Permit will be renewed automatically at the time of renewal of the Commercial License for AROs that have Research as a core activity such as hospitals, higher education institutes, and research and development centers.

4.11	DHCR will seriously consider misconduct in research and/or breaches of ethical standards which will be referred to appropriate bodies for review, investigation, and penalties as applicable.
4.12	Research Involving Human Subjects/Tissue/Samples/Data **4.12.1** All research procedures and protocols conducted within DHCC involving human samples or participants must undergo appropriate ethical scrutiny leading to the protection of the rights, dignity, safety, and well-being of all those involved in the research project, ensuring confidentiality of information about human subjects, cultural sensitivities in the UAE, and the reputation of DHCC, Dubai and the UAE. **4.12.2** Human subjects must be adequately protected during any research project conducted within or in connection with DHCC. Procedures must also be aligned and implemented with due care to follow all DHCR Policies and applicable UAE laws (such as the UAE Medical Liability Law No 4, 2016). **4.12.3** In cases where there is potential conflict between the freedom that the researcher has, within the law, to carry out the research project and the rights of the participants involved in the research project, the researcher must ensure that the participants' interests and rights in the study come first. **4.12.4** The DHCR REC will review all research proposals that involve human subjects to ensure that the principles of the Belmont report that revolve around respect for persons, non-maleficence, beneficence, and justice are met. Hence, the research must **4.12.4.1** ensure the voluntary participation of human participants free from undue influence or coercion; **4.12.4.2** clearly outline the informed consent process; **4.12.4.3** emphasize the fair and non-discriminatory recruitment of human participants especially if recruitment entails vulnerable populations; **4.12.4.4** outline how the risks associated with the research are reasonable and justify them by the expected benefits; **4.7.4.5** have a clear and adequate monitoring plan to ensure the safety of participants as well as indicate how additional protection and safeguards will be applied when vulnerable subject populations are included; and **4.7.4.6** adequately outline how matters of confidentiality of all Patient Health Information are respected and that data storage and quality control are adequately maintained and in compliance with DHCR Health Data Protection Regulation.

5- Procedure Sequence

5.1 New/Renewed Research Permit Submission Procedure

5.1.1 Submitting the Application

Upon receiving notification of an Operator's intent to conduct/ continue to conduct Research activities within DHCC, the Research Department will provide guidance on the correct application form(s) and supporting documents required to obtain/renew a DHCR Research Permit. The applicant will also be advised on the associated fees which will be in accordance with the current DHCR service fees structure (https://dhcc.ae/regulations/service-fees)

Once documents as per the requirements stated in the applicable checklist (https://dhcc.ae/regulations/all) are ready to be submitted, the applicant will send them to the Research Department via email.

5.1.2 Administrative Review: Acknowledging receipt of documents and validating an application for review by the ARC

The Research Department will commence validation of the application on receipt of documents upon which an invoice for Research Permit Application Review will be issued by the DHCR Finance Department. Notification of application validity is issued via email within ten (10) working days from receipt of documents.

In general, an application should be accepted as valid if it meets the following criteria :

5.1.2.1 mandatory documents as per the specified checklist have been provided;

5.1.2.2 the correct application form has been completed and has been signed and dated by the authorized person on behalf of the Operator;

5.1.2.3 applicable supporting documents as required have been provided;

5.1.2.4 all text is in English, and the print is clearly legible; and

5.1.2.5 receipt for payment of Initial Review Fee for Research Permit is provided.

It is the responsibility of the Entity submitting the Application to provide a completed application form and to ensure the accuracy of all information provided. In the case of incomplete Applications, the Research Department will notify the Entity identifying the information that has not been provided and the timeframe within which the Application may be resubmitted. The Entity will not be required to pay an additional fee for resubmitting the Application within the specified timeframe. If the Application is not resubmitted within the time specified, the Application will be considered to be withdrawn and the Applicant will need to submit a new Application together with the applicable fee.

At any time during the review of an Application and prior to the Research Department issuing a Research Permit, the Applicant must promptly notify the Research Department of any modification or change to the information or documentation contained in its Application. Failure of an Applicant to notify the Research Department of any such changes will result in the Application being considered incomplete and withdrawn.

If the notification of changes is received after the Research Department has completed its review of the Application, the Applicant will pay the applicable fee before the Research Department undertakes a further review of the revised Application.

5.1.3 Decisions by the Academic and Research Council (ARC)

Upon review of an application, the ARC Chairperson and/or ARC may:

5.1.31 approve the application for a Research Permit;

5.1.3.2 approve the application for a Research Permit subject to conditions or restrictions as deemed necessary to be included in the Research Permit;

5.1.3.3 defer the decision pending further information; or

5.1.3.4 deny the Application for a Research Permit.

Resubmission of the Research Permit application with relevant fees is required if the Operator fails to respond to the ARC comments within 10 days of receiving said comments.

In the event that the ARC denies a certain Research Permit application, the applicant has the right to appeal the denial decision with the DHCR Appeals Board.

5.1.4 Notification of Decision Regarding Research Permit

The Operator will be notified of all decisions within five (5) working days from the date of ARC decision. Notifications will be sent by email to the responsible persons as listed on the initial application. In case of approval, the Operator will receive an invoice from the DHCR Finance Department for Research Permit Approval.

5.1.5 Issuing Approved Research Permit

Once the new/renewed Research Permit is approved, the Research Department will prepare the Research Permit which will contain the following details:

5.1.5.1 name of the Approved Research Operator;

5.1.5.2 effective date of the Research Permit;

5.1.5.3 term of the Research Permit;

5.1.5.4 Approved Research Activity that the Approved Research Operator intends to conduct; and where applicable any terms, conditions or restrictions included in the Research Permit, as may be specified by DHCR;

	5.1.5.5 approved Research Site where DHCR reserves the right to conduct site assessment visits to ensure the site is suitable for the Approved Research Activity; and **5.1.4.5** Research permit reference number which will be generated by the Research Department.
5.2	**Research Proposal Submission Procedure** **5.2.1 Submitting the Application** Upon receiving notification of an Approved Research Operator's intent to submit a Research Proposal for review, the Research Department will provide guidance on the correct application form(s) and supporting documents required (documents can be accessed on the following link: (https://dhcc.ae/regulations/all) . The applicant will also be advised on the associated fees which will also be advised on the associated fees which will be in accordance with the current DHCR service fees structure (https://dhcc.ae/regulations/all) Once documents as per the requirements stated in the applicable checklist are ready to be submitted, the applicant will send them to the Research Department via email. Research Proposal submissions for REC review must be made at least 10 working days prior to the upcoming REC meeting in order to be included on said meeting's agenda. Submissions 3-9 working days prior to the REC meeting will incur an urgent processing fee where urgent processing does not guarantee approval. **5.2.2 Administrative Review: Acknowledging receipt of documents and validating an application for review by the REC** The Research Department will commence validation of the application on receipt of documents upon which an invoice for Initial Review will be issued by the DHCR Finance Department. Notification of validity is issued via email within ten (10) working days from receipt of documents. In general, an application should be accepted as valid if it meets the following criteria : **5.2.2.1** mandatory documents as per the specified checklist have been provided; **5.2.2.2** the correct application form has been completed and has been signed and dated by the authorized person on behalf of the Operator; **5.2.2.3** applicable supporting documents as required have been provided; **5.2.2.4** all text is in English, and the print is clearly legible; **5.2.2.5** Arabic translation of necessary documents (such as consent form, Patient Information Sheet, Questionnaires etc..) has been provided; and **5.2.2.5** receipt for payment of Initial Review Fee for Research Protocol is provided.

It is the responsibility of the Entity submitting the Application to provide a completed application form and to ensure the accuracy of all information provided. In the case of incomplete Applications, the Research Department will notify the Entity identifying the information that has not been provided and the timeframe within which the Application may be resubmitted. The Entity will not be required to pay an additional fee for resubmitting the Application within the specified timeframe. If the Application is not resubmitted within the time specified, the Application will be considered to be withdrawn and the Applicant will need to submit a new Application together with the applicable fee.

The cut-off point of resubmission of deficient documentation is 10 working days prior to meeting of the REC for standard review and 3-9 working days for urgent review. Applications requiring more than three administrative reviews due to noncompliance with Research Department's comments will incur additional review fees. Submission of altered and/or additional documents following validation of a Research Proposal application by the Research Department and prior to review by the REC will incur additional review fees.

At any time during the review of an Application and prior to the Research Department issuing a Research Proposal decision, the Applicant must promptly notify the Research Department of any modification or change to the information or documentation contained in its Application. Failure of an Applicant to notify the Research Department of any such changes will result in the Application being considered incomplete and withdrawn.

If the notification of changes is received after the Research Department has completed its review of the Application, the Applicant will pay the applicable fee before the Research Department undertakes a further review of the revised Application.

5.2.3 Decisions by the REC

The DHCR Research Ethics Committee (REC) is responsible for review of new Research Proposals, continuing research proposal applications, and any other proposals that require REC members' decisions.

REC decisions include:

5.2.3.1 approval;

5.2.3.2 approval with minor modifications/conditions;

5.2.3.3 decision deferral pending further information/major changes; or

5.2.3.4 denial.

	5.2.4 Notification of Decision Regarding Research Proposal The DHCR Research Department will notify the ARO via email of the REC decisions within 5 working days of the decision. The notification email will include: **5.2.4.1** reasons for REC decisions; **5.2.4.2** committee requested changes to the protocol, informed consent forms and/or other documents; and **5.2.4.3** the frequency of continuing review to be determined by the REC members following review of each protocol. The frequency of continuing review is at least annual unless otherwise agreed upon and depends on the degree of risk, involvement of special population, if previous studies indicated high incidence of adverse events or if the REC believes that close monitoring is required. Resubmission of the Research Proposal application with relevant fees is required if the ARO fails to respond to the REC comments within 10 days of receiving said comments. In the event that the REC denies a certain Research Proposal application, the applicant has the right to appeal the denial decision with the DHCR Appeals Board.
5.3	**REC Approval Criteria** **5.3.1** The DHCR REC is governed by ethical principles described in the following documents: **5.3.1.1** Federal Laws of the UAE; **5.3.1.2** DHCR Regulations, Rules, Standards, and Policies; **5.3.1.3** World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects; **5.3.1.4** International Conference on Harmonization Good Clinical Practice; **5.3.1.5** The Belmont report that revolves around respect for persons, non- maleficence, beneficence, and justice. **5.3.2 Criteria for Review and Approval** **5.3.2.1** Risks to the Subjects must be minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose Human Subjects to Risk; and whenever appropriate, by using procedures already being performed on Human Subjects for diagnostic or treatment purposes. **5.3.2.2** Risks to a Human Subject must be reasonable in relation to the anticipated benefits to the Subject and the importance of the knowledge that may reasonably be expected to result. **5.3.2.3** The selection of Subjects must be equitable. **5.3.2.4** Informed consent must be obtained from each prospective Human Subject or the

	Subject's representative, as applicable, before any Research related procedure, in accordance with DHCR Regulations and applicable Standards and Policies. **5.3.2.5** Informed consent must be appropriately documented, in accordance with evidence based best practices and using an approved form and patient information sheet. Arabic translation of the informed consent, patient information sheet, and any other material that is to be viewed and used by study Subjects is mandatory. **5.3.2.6** The Protocol includes adequate provision for Monitoring the data collected to ensure the safety of Human Subjects. **5.3.2.7** There are adequate provisions to protect the subject's privacy and maintain confidentiality of research data. **5.3.2.8** There are appropriate provisions for compensation for Human Subjects. **5.3.2.9** When some or all of the Human Subjects are likely to be susceptible to coercion or undue influence, there must be additional safeguards to ensure protection of the rights and welfare of these Subjects.

6- Research involving Children, Vulnerable Adults, Dependents, Pregnant Women, Prisoners, and Others

6.1	Children, vulnerable adults, pregnant women, fetuses, neonates, prisoners, students, employees, elderly, refugees, prisoners, disabled subjects or anyone who is economically, socially or educationally disadvantaged are all considered special population and any research involving these groups would require additional protections and institution oversight. DHCR is committed to the protection of the rights of these vulnerable populations as participants in research studies and special care has to be taken as these subjects may be more vulnerable to coercion and inappropriate influence such that their voluntary participation or informed consent could be compromised.
6.2	In cases where the participant is legally incapable of providing consent or is a minor, the researchers must obtain approval from the participants' parent(s) or legal guardian(s), in addition to seeking the participant's agreement, explaining the research project and the role of the participant, while ensuring the participant's best interests are served.
6.3	Any research involving children should comply with Articles 3 and 12 of the United Nations Convention on the Rights of the Child and UAE laws on protection of children. UN Convention Article 3 stipulates that the best interest of the child must be the primary consideration in all

	actions concerning children and UN Convention Article 12 stipulates that children who are capable of forming their own views should be granted the right to do so freely in all matters affecting them, appropriate with their age and maturity. Research involving children should also abide by relevant UAE laws on protection of the rights of children - including but not limited to Federal Law No. 3 of 2016 concerning child rights, also known as *Wadeema's Law* - and ensure that no potential Risk(s) to the participants are associated with the research study. Following evaluation of the age, maturity, and psychological state of the child, assent from the child and parental permission (parallel to informed consent) should be obtained.
6.4	Any research involving a vulnerable adult (who is incapacitated or dependent due to cognitive, medical, economic, social, or situational factors) should take the appropriate precautions to ensure that they have not been subjected to undue influence to participate by either the dependents, the research team, or anyone else.
6.5	Any research involving pregnant women should abide by relevant UAE laws and ensure the safety and health of the mother and the fetus first and foremost. Therefore, as general guidelines, research on pregnant women is only acceptable if the research holds direct benefits to both the mother and the fetus or has no Risk or minimal Risk to either. In addition, the research should result in research findings/data that cannot be obtained by other means. Moreover, consent should be obtained from both partners except in special circumstances. For underage children who might be pregnant, both assent and parental permission need to be obtained for their participation in any research study. No monetary or other inducements may be offered to a pregnant woman to terminate her pregnancy for research purposes. Researchers involved in the research project are not allowed to make any decisions pertaining to the pregnancy or the viability of the fetus.

6.6	Any research involving prisoners should abide by the relevant UAE laws and it should ensure the safety and rights of prisoners. Therefore, as general guidelines, research on prisoners is only acceptable if the research project addresses the possible causes, effects, and processes of incarceration, and of criminal behavior, or focuses on prisons as institutional structures or on prisoners as incarcerated persons provided that the research presents no more than minimal Risk or inconvenience to the participants. In addition, if the research project investigates the conditions affecting prisoners (for example, vaccine trials or any other research that tends to be more prevalent among prisoners, such as on hepatitis, or research on social and psychological problems like alcoholism, drug addiction, and sexual assaults, etc.), then appropriate experts should be adequately consulted prior to the study. This kind of research may also require additional approvals from other UAE agencies.

7- Responsibilities of the Principal Investigator (PI)

The research study PI must fulfill the following duties and responsibilities:

7.1	To ensure that all research studies have obtained ethical approval by the DHCR REC and that the research is carried out in accordance with the DHCR Ethics Policies and Procedures, and in compliance with UAE laws on individual and public safety and Good Clinical Practice.
7.2	As the DHCR REC relies on the information provided in the application form(s), it is expected that all information is complete, truthful, and accurate including declaration of Significant Financial Interest and/or Conflict of Interest pertaining to the PI or any other member of the research team. Failure to do so could be considered research misconduct and may result in Penalty.
7.3	It is important to understand that regardless of the decision by the DHCR REC on a specific research study, it is ultimately the responsibility of the PI and the research team themselves to make sure that the research study is carried out at the highest ethical standard.
7.4	Where a DHCA-licensed Healthcare Professional is engaged in joint research projects with other universities or institutions outside of DHCC ethical approval must be sought from all joint institutions as necessary. Again, the PI must ensure that all ethical approvals have been obtained prior to the start of the research project.
7.5	Registering the approved study on www.clinicaltrials.gov and including DHCC as the study site.

7.6	The PI must ensure that procedures used: **7.6.1** are consistent with sound research design and Good Clinical Practice; **7.6.2** do not unnecessarily expose subjects to Risk/harm; **7.6.3** safeguard the privacy of research participants; and **7.6.4** ensure confidentiality of participant information/data. All personal information should be encoded or made anonymous from the beginning of the data collection and codes kept separately. In certain cases guarantees of privacy and confidentiality may be overruled in order to ensure protection of the research participants' physical and psychological safety and well-being.
7.7	Once the research has been approved the PI must keep the DHCR Research Department and the REC updated on any issues that arise during the conduct of the study. This includes but is not limited to amendments, progress reports, and safety information reporting. The PI must report any Serious Adverse Event immediately to DHCR whether it occurs inside or outside DHCC.
7.8	If the research study is of an interventional nature in which there is potential harm to the research subjects the PI must allocate a part of the study budget to compensate affected subjects for research related injury (i.e. purchase liability insurance for such cases). In addition, the PI should address the method and manner of compensation when study subjects receive the same.
7.9	The PI must ensure the integrity of the data.
7.10	The PI must oversee all aspects of trial management, data handling, record keeping and ensuring protocol compliance.
7.11	The PI must allocate responsibilities by defining, establishing, and assigning all trial-related duties and functions.
7.12	The PI must ensure record access for monitoring, audits, REC reviews, and regulatory inspection.
7.13	The PI must prepare and provide DHCR with research study reports whether the study is completed or prematurely terminated.
7.14	The PI must establish systems of quality assurance and quality control with written Standard Operating Procedures (SOPs).
7.15	The PI must oversee regulatory requirements of the investigational product including safety and efficacy, updating the Investigator's Brochure as required, compliance with Good Manufacturing Practice, and appropriate labelling, packaging, and coding of all investigational products.

7.16	The PI must establish a system for ongoing research study monitoring.
7.17	The PI must ensure that he/she as well as all research team members maintain valid Good Clinical Practice certification for the duration of the research study. Good Clinical Practice certification is valid for two (2) years from date of issuance.

8- Responsibilities of the Sponsor

Research study sponsors must fulfill the following duties and responsibilities:

8.1	Quality management and monitoring including: risk identification, evaluation, control, communication, and reporting. In addition to identification of critical processes and data. A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a Contract Research Organization (CRO), but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor. The CRO should implement quality assurance and quality control;
8.2	Quality assurance and quality control with written Standard Operating Procedures (SOPs);
8.3	Selection of reliable vendors and timely delivery of investigational products to the Investigator(s);
8.4	Trial management, secure data handling, record keeping and ensuring protocol compliance;
8.5	Submitting regulatory documents to both research ethics committees/institutional review boards (REC/IRBs) and regulatory/competent authorities;
8.6	Overseeing regulatory requirements of any/all investigational product(s) including safety and efficacy, updating the Investigator's Brochure as required, compliance with Good Manufacturing Practice, and appropriate labelling, packaging, and coding of all investigational products;
8.7	Adequately training all study personnel, participants, and vendors as necessary;
8.8	Appointment of appropriately qualified clinical personnel readily available to advise on trial related medical questions or problems. Each investigator should be qualified by training and experience and should have adequate resources to properly conduct the trial for which the investigator is selected;
8.9	Ensuring the integrity of the data;
8.10	Allocation of responsibilities by defining, establishing, and assigning all trial-related duties and functions;

8.11	Compensation to subjects and investigators whereby the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the ARO against claims arising from the trial except for claims that arise from malpractice and/or negligence. In addition, the sponsor's policies and procedures should address the costs of treatment of trial subjects in the event of trial-related injuries, as well as untoward side-effects, and the method and manner of compensation when trial subjects receive the same;
8.12	Financing of the study whereby the financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/ARO and a signed copy provided to DHCR REC for review.
8.13	Notifying DHCR and any other relevant regulatory authorities of study commencement, amendments, close out, premature termination, suspension, adverse events or any deviation from/noncompliance with the REC-approved protocol/Good Clinical Practice or any material findings that may alter the REC's approval to continue the trial;
8.14	Ensuring secure record access for monitoring, audits, REC reviews, and regulatory inspection;
8.15	Safety evaluation of the study and associated investigational products. All adverse drug reactions (ADRs) that are both serious and/or unexpected must be reported to DHCR REC in compliance with DHCR requirements and ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting;
8.16	Research study monitoring and audit including selection of qualified monitors/auditors, establishing a monitoring/audit plan;
8.17	Preparing and providing DHCR with research study reports whether the study is completed or prematurely terminated;
8.18	It is the responsibility of the Sponsor to ensure that the Investigator as well as all research team members maintain valid Good Clinical Practice certification for the duration of the research study. (N.B. Good Clinical Practice certification is valid for two (2) years from date of issuance.)

9- Human Genetic Research

The study of the human genome is the key to understanding the blueprint of human diseases and the advancement of medicine and any human genome research studies taking place in DHCC must abide by the following:

9.1	Human genome, exome, and/or RNA sequencing and/or analysis must be documented in an agreement between the Investigator/ARO and the sequencing facility; and a signed copy provided to DHCR REC for review. Whenever feasible, genetic samples are to be analyzed by facilities/labs within the UAE. If the required service is not available within the UAE then the samples may be sent abroad with precautions taken to safeguard the safety, security, confidentiality, and integrity of the samples and the data generated.
9.2	The agreement must include but is not limited to the following: 9.2.1 The type of samples that will be collected and the method of collection; 9.2.2 The frequency of sample collection and submission by Investigator/ARO to the sequencing facility; 9.2.3 Whether or not biological replicates will be required; 9.2.4 The method of sample submission and whether or not a Bioanalyzer is required; 9.2.5 The method of sample storage and maintenance of sample integrity by the genetic sequencing facility; 9.2.6 The duration of sample storage; 9.2.7 Whether or not excess sample material can be retrieved by the Investigator/ARO and the method and timing of the retrieval; 9.2.8 The method of sample destruction following sequencing and analysis; 9.2.9 The method by which the genetic sequencing facility will release the data to the Investigator/ARO once the samples are analyzed; 9.2.10 The duration of data retention and the method of subsequent destruction by the genetic sequencing facility; 9.2.11 The type of genetic sequencing; 9.2.12 The depth of genetic sequencing; 9.2.13 The confidentiality and nondisclosure obligations imposed by the sequencing facility on its staff; 9.2.14 The turnaround time and deliverables; 9.2.15 A declaration by the sequencing facility that samples and/or data will not be used for any purpose beyond what is stated in the agreement; and 9.2.16 The cost of the service.
9.3	The Investigator and the ARO must abide by all UAE federal and local laws, policies, and regulations.

9.4	Genetic studies and their subsequent results must not be used in any manner that may be harmful or contrary to UAE federal and local laws or the UNESCO Genome Declaration of 1997.
9.5	Samples and/or parts of samples, as well as data from previously approved research studies must not be used for any further research or analysis without prior approval from DHCR REC.
9.6	The genetic sequencing facility credentials including but not limited to license, registration, and accreditation must be submitted as part of the genetic research study application for review by the DHCR Research Department and the DHCR REC.

10- Definitions:

10.1	**Approved Research Activity:** a research activity for which a Research Permit has been granted.
10.2	**Approved Research Operator:** an Entity that holds a valid Research Permit issued by DHCR to conduct research activities in accordance with the applicable DHCR Rules, Standards and Policies.
10.3	**Approved Research Site:** site or location within DHCC, including the physical facility or facilities associated therewith, at which an Approved Research Operator is permitted to conduct Approved Research Activities under its Research Permit.
10.4	**Approved Use:** the use of a drug, biologic or medical device that has been approved for one or more specific indications by a duly constituted regulatory agency in a jurisdiction recognized for this purpose by DHCR.
10.5	**Audit:** a systematic and independent evaluation of a research and documents to determine whether the research was conducted in accordance with the requirements of the Research Regulation, any applicable Rules, Standards and Policies, and the Protocol approved for such research.
10.6	**ARC:** Academic and Research Council.
10.7	**CEO:** Chief Executive Officer of DHCR.
10.8	**Conflict of Interest:** a divergence between an individual's private interest and his professional obligations. A potential or actual Conflict of Interest, either financial or non-financial, exists when a significant interest could affect the design, conduct, or reporting of research or educational activities
10.9	**DHCC:** Dubai Healthcare City.

10.10	**DHCR:** Dubai Healthcare City Authority – Regulatory the independent regulatory arm of Dubai Healthcare City Authority (DHCA), the governing body of Dubai Healthcare City (DHCC) free zone - a health and wellness destination.
10.11	**Document** and **Documentation:** information stored in any form of writing, code, or visual depiction and the manner in which such information is stored is irrelevant for the purpose of deeming the information to constitute a "document" for the purpose of this definition.
10.12	**Entity:** an organization, institution, or corporation other than a natural person.
10.13	**Human Biomedical Research:** any systematic investigation, including research development, testing and evaluation that involves the use of either an investigational product in human subjects, the use of identifiable human tissue or Patient Health Information, with the objective of developing or contributing to generalizable knowledge.
10.14	**Human Subject:** a living individual about whom an Investigator conducting an Approved Research Activity obtains either data through intervention and/or interaction with the individual or by obtaining that person's patient health information.
10.15	**Informed Consent:** a process by which a Human Subject's, or where that person is a Vulnerable Subject, that person's Representative, voluntary confirmation of his willingness to participate in a particular research study, after having been informed of all aspects of the study procedures that are relevant to such Human or Vulnerable Subject's decision to participate.
10.16	**Interventional Study:** Human Biomedical Research in which Human Subjects are assigned to receive specific diagnostic, therapeutic, or other types of biomedical or behavioral intervention.
10.17	**Investigational Product:** any investigational drug, biologic or medical device being tested or used as a reference in Human Biomedical Research, including a product with a Marketing Authorization when used or assembled (formulated or packaged) in a way different from the Approved Use, or when used for an indication that is not an Approved Use, or when used to gain further information about an Approved Use.
10.18	**Investigators:** the Principal Investigator and co-investigators collectively. The Principal Investigator is the individual responsible and accountable for designing a Protocol, and conducting and Monitoring of an Approved Research Activity in accordance with the Protocol. The co-investigator is an individual member of a research team, qualified by training and experience, designated and supervised by the Principal Investigator to perform critical research-related procedures and/or to make important research-related decisions.

10.19	**Investigator's Brochure**: a compilation of the clinical and pre-clinical data on an Investigational Product that is relevant to the study of the Investigational Product in Human Subjects
10.20	**Monitoring**: the act of overseeing the progress of Approved Research Activities, and of ensuring that it is conducted, recorded and reported in accordance with the approved Protocol, the Research Regulation and any applicable Rules, Standards and Policies;
10.21	**NOC:** No Objection Certificate.
10.22	**Patient Health Information:** information about a patient, whether spoken, written, or in the form of an Electronic Record, that is created or received by any licensee, that relates to the physical or mental health or condition of the patient, including the reports from any diagnostic procedures and information related to the payment for services.
10.23	**Penalty**: the penalty imposed by DHCR in accordance with the applicable regulations.
10.24	**Protocol:** the document that describes the objective(s), design, methodology, statistical considerations and organization of the research activity.
10.25	**Records**: all papers, records, recorded tapes, photographs, statistical tabulations or other documentary materials or data, regardless of physical form or characteristics, including in written or electronic form
10.26	**Representative:** the Human Subject's legal or personal representative who is authorized to act on behalf of a prospective Vulnerable Subject, with regard to the Human Subject's participation in research.
10.27	**REC:** Research Ethics Committee.
10.28	**Research Permit:** a permit issued by DHCR to an Entity authorizing it to conduct the Approved Research Activity.
10.29	**Risk:** the probability of harm or injury, whether physical, psychological, social, or economic, occurring as a result of participating in Approved Research Activities.
10.30	**Serious Adverse Event:** any unanticipated incident involving Risks or injury or death of Human Subjects that may present itself during the course of Approved Research Activities.
10.31	**Significant Financial Interest**: anything of a monetary value or an Equity Interest in an Entity held by an Investigator during the time he is carrying out the research and for 1 year following completion of such investigation.

10.32	**Sponsor:** pharmaceutical company, academic institution or any other Entity that takes responsibility for the initiation of research and/or arranges for the payment, if any, of the research.
10.33	**Special Population** includes Vulnerable Subjects and others with special needs and includes pregnant women and their in utero fetuses
10.34	**Vulnerable Subject:** vulnerable Human Subject with diminished competence and/or decision making capacity due to age, physical or medical conditions, or social-economic status.