Document Type: Policy	**Code:** DHA/HRS/HPSD/HP-19	**Version Number:** 1.1
Document Title: Clinical Trials Policy	**Issue Date:** 10/04/2023	**Effective Date:** 12/06/2023
Ownership: Medical Education and Research Department		
Applicability: All Healthcare Facilities licensed under the jurisdiction of Dubai Health Authority		

1. Purpose:

1.1. The Clinical Trials Policy aims to fulfil the following overarching DHA Strategic Priorities (2022-2026):

1.1.1. Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.

1.1.2. Make Dubai a lighthouse for healthcare governance, integration and regulation.

1.1.3. Foster healthcare education, research and innovation.

1.2. To regulate the conditions and requirements to approve conducting clinical trials in DHA licensed health facilities.

1.3. To establish clear and specific requirements for health facilities conducting clinical trials.

1.4. To protect the rights of human subjects participating in clinical studies in accordance with international standards of research ethics.

2. Scope:

2.1. Clinical trials in DHA licensed health facilities.

3. Definitions and Abbreviations:

Clinical trial team: Individuals, identified by the principal investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial team is to manage participant recruitment and enrollment, to maintain consistent study implementation, data management, and to ensure integrity and compliance with regulatory and reporting requirements. These individuals may also seek informed consent from prospective participants, enroll and meet with research participants, and collect and record information from research participants. Clinical trial team members may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

Clinical Trials: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioural outcomes.

Dubai Scientific Research Ethics Committee: Is a Central Scientific and Ethical Committee for the Emirates of Dubai. The primary objective of the DSREC is to that issues ethical approval for clinical trials through independent and timely review of research projects involving human subjects in addition to ongoing ethical oversight, monitoring and advice to protect the mental, physical welfare,

rights, and safety of participants of research. This is in accordance with the DHA code of ethics, the ICH-GCP guidelines, and ethical principles described in the Declaration of Helsinki and Code of Federal Regulations. Legal, Religious, local and Cultural factors are also considered when taking decisions.

Medical Education and Research Department: is the department within Dubai Health Authority responsible for provision of medical education, research and continuing professional development of healthcare experts in the United Arab Emirates.

Health facility: A DHA licensed facility that provides integrated and comprehensive health care to patients according to the international standards.

Principal Investigator: is the primary individual responsible for the preparation, conduct, and administration of a research project at a study/trial site in compliance with applicable laws and regulations and facility policy governing the conduct of research.

DHA: Dubai Health Authority.

DSREC: Dubai Scientific Research Ethics Committee.

GCP: Good Clinical Practice.

ICH: The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

MERD: Medical Education and Research Department.

4. Policy Statement:

4.1. All DHA Licensed Health Facilities willing to conduct clinical trial shall obtain approval from Medical Education and Research Department (MERD).

4.1.1. Fill and submit the Dubai Scientific Research Ethics Committee (DSREC) Application Form. (**Appendix 1**)

4.1.2. Fill and submit the Undertaking Letter. (**Appendix 2**)

4.1.3. Ethics submission documents as listed on Dubai Scientific Research Ethics Committee online page.

4.2. Clinical study/trial may be carried out in the below facility categories:

4.2.1. Outpatient care setting

4.2.2. Inpatient care setting

4.2.3. Clinical laboratories.

4.3. Health Facilities conducting clinical studies shall ensure:

4.3.1. Availability of scientifically qualified research team that fulfil the clinical trial purpose.

4.3.2. Attainment of Good Clinical Practice Certificate training by all clinical trial team members.

4.3.3. Availability of a policy/process in place that ensures ability to deal with emergency situations that may result from the use of experimental products in clinical studies, and has

to provide participants with a method of communicating with the principal investigator if necessary.

4.3.4. Availability of consent for the participation of the investigator and for the conducting of the trial.

4.3.5. Approval from Dubai Scientific Research Ethics Committee (DSREC) to conduct the clinical trial.

4.3.6. Adherence to the DSREC clinical trial requirements.

4.3.7. Availability of a designated site for conducting clinical studies, including a site for examining participants and taking their data, storing confidential documents, and storing experimental products or lab samples if required.

4.3.8. Indemnity Insurance coverage for all study participants.

4.3.9. Logistic support to ensure the conduct of clinical studies in accordance with the protocol approved by the DSREC, and this includes confidentiality of the participants and their data and handling the experimental products according to the instructions accompanying the product.

4.4. All clinical investigators and clinical trial team members involved in the design, conduct, oversight, or management of clinical trials shall be trained in Good Clinical Practice (GCP).

4.4.1. Recipients of GCP training are expected to retain documentation of their training.

4.4.2. GCP training should be refreshed at least every three years.

4.5. Research misconduct and failure to abide to the rules and regulations will result in revocation of the facilities approval.

5. References

5.1. European Commission (2021). *Clinical Trials*. [online] Available at: https://ec.europa.eu/health/human-use/clinical-trials_en (Accessed 2 June 2021)

5.2. National Institute of Health (2021). *NIH's Definition of a Clinical Trial*. [online] Available at: https://grants.nih.gov/policy/clinical-trials/definition.htm (Accessed 2 June 2021)

5.3. National Institute of Health (2021). *Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials.* [online] Available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html (Accessed 2 June 2021)

5.4. Department of Health Abu Dhabi (2020). *DOH Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices.*

5.5. Department of Health Abu Dhabi (2020). *DOH Standard on Human Subject Research.*

Appendices:

Appendix 1 - Dubai Scientific Research Ethics Committee Application Form

1. Instructions

Fill in this application form, sign it electronically then send it to DSREC@dha.gov.ae considering the below:

- ✓ The application must be clearly legible
- ✓ Typing is a must. No handwritten form will be accepted
- ✓ The modification of the original content of the form is strictly prohibited.
- ✓ All sections of the application form must be completed
- ✓ Write "Not Applicable" wherever appropriate

2. Principle Investigator's Details (undergraduate students can't be principle investigators on a clinical study)

2.1 Name:		**2.2 Staff ID:** (applicable for DHA staff)	
2.3 Designation:		**2.4 Unit/Department:**	
2.5 Institution:		**2.6 Email:**	
2.7 Contact no. Office:		**2.8 Mobile:**	

2.9 Does the principle investigator or other key personnel have any conflict of interest in this study?

☐ **No** ☐ **Yes, please specify**_____

3. Co-Investigators and Study Staff

3.1 Are co-investigators involved in this study?	☐ **Yes**, please fill below table	☐ **No**, why? _____

Title	Name	Designation	DHA Staff ID	E-Mail/Contact	Unit/Dept	Role in the study

** you may add more rows if required

4. Research/Study Details

4.1 Title:

_____

4.2 Short Title (if applicable):

_____

4.3 Proposed Study Start Date	dd/mm/yyyy	**4.4 Proposed Study End Date**	dd/mm/yyyy
4.5 Retrospective Study Period *(From) only if applicable:*	dd/mm/yyyy	**4.6 Retrospective Study Period (To)** *only if applicable:*	dd/mm/yyyy

4.7 Type:

☐ Drug Study ☐ Device Study ☐ Chart/Records Review

☐ Biomedical Research ☐ Health Related Research ☐ Community-Based

☐ Social and Behavior Research ☐ Research with Genetic Material ☐ Genomics-Related Research

☐ Other: _____

4.8 Summarize the background and hypothesis of the study:

_____

_____

4.9 What are the primary and secondary objectives of the study?

_____

_____

4.10 Why is this research important? What contributions will it make?

_____

_____

4.11 Has this research proposal been approved by an Institutional Review Board (IRB) or Research Ethics Committee elsewhere? ☐ Yes ☐ No

If 'Yes', please attach a copy of the approval and provide the following information:

a. Name of institution that reviewed this research proposal _____

b. Address of reviewing institution _____

4.12 Has this study been done elsewhere? ☐ Yes ☐ No

If 'Yes', how does this differ from the ones done earlier?

_____

4.13 Is this a multi-center trial? ☐ Yes ☐ No

If yes, which are the other centres involved? _____

4.14 List the research site(s), where the study is to be conducted and the contact person details of each site (title, name, mobile, email, etc.):

_____

_____

4.15 Will this study involve human subjects? ☐ Yes ☐ No ☐ Not-applicable

If 'Yes', will you have direct contact or intervention with them? ☐ Yes ☐ No

(e.g., as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?)

4.16 Research Population:

a. Research population and sample size calculation:

_____

b. Expected total number of participants in the study

_____

c. Age range of participants

_____

d. How will participants be included in the study?

_____

e. If randomization is used, please explain how this will be done

_____

f. How much time will a subject have to dedicate to the project beyond that needed for standard treatment?

_____

g. If normal volunteers are involved, please explain how many will be selected and the method of selection employed?

_____

4.17 This study will involve the following subject types (check mark the applicable subject type):

☐ Normal Volunteers	☐ Subjects Incapable of giving Consent
☐ In Patients	☐ Prisoners or Institutionalized Individuals
☐ Out Patients	☐ Fetuses
☐ Patient Controls	☐ Infants (0 -3 Y)
☐ Students	☐ Children (3-12Y)
☐ Cognitively Disabled	☐ Minors (Under Age 18)
☐ Physically Disabled	☐ Over Age 60
☐ Pregnant Women	☐ Other Potentially Elevated Risk Populations

4.18 What are the inclusion criteria?

_____

4.19 What are the exclusion criteria?

_____

4.20 Please specify any incentives, compensation or treatment the participants will receive through participation in this study:

_____

4.21 Does this project call for? (Check mark all that applies):

☐ Use of Voice, Video, Digital, or Image Recordings?

☐ Advertising for subjects?

☐ More than Minimal Risk?

☐ More than Minimal Psychological Stress?

☐ Extra Costs to the subjects (tests, hospitalization, etc.)?

4.22 Are there any predictable risks to the subjects of physical or psychological pain or discomfort, or risk of injury of any kind? ☐ Yes ☐ No ☐ Cannot Predict

If 'Yes' or 'Cannot predict', describe the possible areas of risk. Outline briefly any steps taken to minimize the possibility of pain, discomfort or injury and procedures for determining levels of discomfort at which you will terminate the participation by the subject in the research:

_____

4.23 This project involves the use of (Check mark all that applies):

☐ An Investigational New Drug (IND) or an approved drug for an unapproved indication.

Drug name and company _____

☐ An Investigational Medical Device or an Approved Medical Device for An Unapproved Use

Device name and manufacturer _____

☐ Radiation or Radioisotopes

☐ Blood, total amount of blood needed _____ over time period (days)_____

☐ rDNA or Biohazardous materials

☐ Human Tissue or Cell Lines

4.24 If a drug or a device will be used for the study:

Is the drug or the device approved (registered) by DHA or MOH? ☐ Yes ☐ No

If No,

a. Is the drug or the device approved by any major International Organizations, e.g. FDA, EMEA?

☐ Yes ☐ No

b. Is the documentation on the provision of the unregistered drug or the device to the site submitted?

☐ Yes ☐ No (If no please provide the explanation

c. Is the MOH UAE declaration for the entry of the unregistered drug or the device submitted?

☐ Yes ☐ No (If no please provide the explanation) _____

d. Provide details of any known side effects, which may result from the investigational drug or device.

_____

e. If it is a drug, what phase of research the drug has reached to date?

☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Post marketing study

For clinical trials please complete the Clinical Trial Undertaking Letter.

4.25 Is this a double-blinded study? ☐ Yes ☐ No

If yes,

a. Is the code for unblinding in case of emergency available at both the investigator (e.g. hospital) and sponsor sites?

☐ Yes ☐ No, justify_____

b. Format in which code breaks for clinical trials are supplied

☐ Sealed envelopes

☐ Scratch cards

☐ Tear off label on the drug container which will be removed when dispensing the trial drug and place on the drug accountability form

☐ Interactive voice response system – user identity and password are required to access such system

☐ 24-hour telephone number provided by the sponsor

4.26 Does the project require special data collection (e.g., interview, questionnaire, case record forms)?

☐ Yes ☐ No

If Yes, please attach a copy

4.27 What special training or qualifications are required for data gatherers? Who will provide training?

**As per DSREC SOP, it is mandatory to submit the certificate for Clinical trial with certificate validity of two years.*

Training name	**Certified**
ICH GCP	☐ Yes ☐ No
NIH	☐ Yes ☐ No
Other (Specify):	☐ Yes ☐ No

4.28 Data handling:

a. Who will have access to the data?

_____

b. Will all personally identifying data be held confidential? ☐ Yes ☐ No

c. Does the project require the linkage of project data on available subjects with other individually identifying data from outside the facility or division? ☐ Yes ☐ No

If yes, describe the other data sources and types of data used:

_____

d. What steps are being taken or will be taken to ensure that no information that may identify an individual be released?

_____

e. How will the subjects' rights to privacy and safety be protected? Describe measures that will be taken to protect the confidentiality of data containing patient-identifying information:

_____

f. Will any patient identifiable information be provided to an external study sponsor?

☐ Yes ☐ No ☐ Not-Applicable, there is no external study sponsor

4.29 Anonymity and Confidentiality:

a. Will the anonymity (*protection of the identity of participants*) of participants be protected?

☐ Yes (completely) ☐ Yes (partially) ☐ No

If 'Yes', how will anonymity be protected and how will this be explained in the consent process?

_____

If 'No', justify why loss of anonymity is required and explain how this will be explained in the consent process:

_____

b. Will you provide confidentiality *(protection, access, control and security of the data and personal information*) to the participants and their data? ☐ Yes ☐ No

If 'Yes', how will confidentiality be protected and how will this be explained in the consent process?

_____

If 'No', justify the lack of confidentiality and explain how this will be explained in the consent process.

_____

4.30 Informed Consent. It is DSREC's policy to have written consent for all projects involving human participants.

Please ensure that information sheet and Consent Form includes all the essential elements as per the DSREC Information sheet and consent form template. Submit the same with its Arabic translation. The text description should be the same in both English and Arabic documents.

Other languages to be provided if needed.

4.31 If a signed written consent will not be obtained, explain what you will do instead and why? Additionally, Provide a request for "Waiver of written Consent with a justification for the same"

_____

4.32 What are the provisions made to obtain informed consents in case the participants were of minors or adults incapable of giving consent for themselves?

_____

4.33 Do you expect this research to be used for commercial purposes? ☐ Yes ☐ No

If 'Yes', explain how will this information be declared and explained to the participants in the consent process and to the DSREC:

_____

4.34 Is this study funded? ☐ Yes ☐ No

If 'Yes':

a. What is the nature of the fund? ☐ Grant ☐ Contract/Agreement ☐ Other_____

b. Full name of sponsor / funding source: _____

c. Contract/agreement/grant (attach a copy)

5. Principle Investigator

Your signature indicates that you agree to abide by all policies, procedures, regulations and laws governing the ethical conduct of research involving humans.

Signature of the Principle Investigator

(print name)

(signature)

(date)

6. Head of Department of Study Site

I have read this application and believe it to be scientifically and ethically sound. I approve the research design. I give my consent for the application to be forwarded to the Office of Dubai Scientific Research Ethics Committee with my recommendation that it be approved.

Signature of Head of the Department of the study site:

(print name)

(signature)

(date)

AND/OR

Signature of the Center's CEO

(print name)

(signature)

(date)

7. If this is a supervised work (applies to medical residents/students):

Supervisor's Title/ Name: _____

Position/Depart: _____

Contact Nos.: _____

Email: _____

Supervisor's signature _____ Date _____

Your signature indicates that you have reviewed and approved the proposal, assisted the medical resident in the preparation of this application and agrees to be responsible for the ethical aspects of the project.

Appendix 2 - Undertaking Letter to Conduct Human Subjects Research

Signed letter should be sent to DSREC@dha.gov.ae

Facility Name: **DHA Health Facility License number:**
1. Our facilities/ facility intend to conduct Human Subjects Research*
2. Our facilities/ facility will apply and follow Research Ethics as mandated by DHA.
3. We certify that our Facility/Facilities will maintain the availability of scientifically qualified research team that fulfil the clinical trial purpose.
4. We certify that our facility/facilities will report to DHA, through periodic progress reports or upon DHA request, a clinical trial progress report.
5. We certify that our facility/facilities will immediately report to DHA the occurrence of any serious adverse event.
6. We certify that our facility/facilities will immediately report to DHA any serious breaches of approved research protocols or conditions or principles of Good Clinical Practice (ICH GCP).
7. We certify that our facility/facilities will immediately report to DHA any provision of false or misleading information in an application submitted for ethical approval.
8. We certify that our facility/facilities holds appropriate human subjects research indemnity insurance covering all adverse outcomes for individuals who are the subject of the research, all other potential liabilities of the Institution, and all potential liabilities of individual clinicians and researchers employed by, or contracted to, the Institution.
*Human Subjects Research includes studies of physiological, biochemical or pathological process, or of the response to a specific intervention – whether physical, chemical or psychological – in healthy subjects or in patients or on Human Tissue, controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation,

studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures, and/or studies concerning human health-related behaviour in a variety of circumstances and environments.
☐ Agree ☐ Disagree
Name of Authorized Official: Title: Phone: Email: Signature & Stamp:
Official signature and agreement to this form means that you read and understand the contents and hereby abide by the mentioned points regarding the Department of Health Regulations.