Document Type: Policy	**Ref No:** HRS/HPSD/CTP/01/2021	**Version Number:** 1
Document Title: Clinical Trials Policy	**Issue Date:** 25/07/2021	**Effective Date:** 25/07/2021
Ownership: Medical Education and Research Department		
Applicability: All Healthcare Facilities licensed under the jurisdiction of Dubai Health Authority		

1. Purpose:

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

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

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

1.4. To monitor the commitment of the facility to the research ethics of clinical trials.

1.5. Encourage Clinical Trials in Dubai's Healthcare Sector.

2. Scope:

2.1. Clinical trials in DHA licensed health facilities.

3. Definitions and Abbreviations:

Clinical trial staff: Individuals, identified by the principal investigator, who are responsible for study coordination, data collection and data management. The central focus of clinical trial staff 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 staff 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 Application Checklist to Conduct Human Subjects Research Facilities. (**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 staff 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- Application Checklist to Conduct Human Subjects Research Facilities

The filled form should be sent to DSREC@dha.gov.ae

Facility Name:

DHA Health Facility License number:

SL#	Requirement	Yes	No	Details
Licensing and Accreditation				
1.	Services/Medical Specialties provided by the facility.			Provide a detailed list of services and medical specialties available at the facility.
2.	Facility Accreditation.			Provide Accreditation Certificate
3.	Previous medical liability cases involving the facility or research misconduct.			Provide details.
Qualified personnel				
4.	Availability of scientifically qualified research team.			Provide staff DHA License details
5.	Good Clinical Practice Certificate training for all staff involved in research.			Provide training certificates.
Facility Logistics				
6.	Availability of in-house Clinical Laboratory.			Provide details on laboratory services, technical details, list of clinical laboratory staff.
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.			Provide labelled layout and drawings of the areas.
8.	Availability of space to retain documents if required.			Provide labelled layout and drawings of the areas.
Emergency Situations and Insurance				
9.	Ability to deal with emergencies that may result from the use of experimental products in clinical studies.			Provide internal policies and procedures.

10.	Available means for patients to communicate with the principal investigator in case of emergency involving research participants.			Provide internal policies and procedures.
11.	Ability to provide Indemnity Insurance coverage for all study participants			Provide Insurance details (sponsor details if applicable) and policy (if available)

Note: *DHA will review the above and might request further information from your facility. Physical inspection will be conducted to ensure the accuracy of the provided details.*

For DHA Official Use Only	
Evaluation Report	**……(*Facility Name*) has (*met/not met/partially met*) all the required criteria set by Dubai Health Authority.**
Additional Comments if Any:	

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.