DOW UNIVERSITY OF HEALTH SCIENCES

STANDARD OPERATING PROCEDURE

Policy for Registration in DUHS Trial Registry

	NAME	DESIGNATION	SIGNATURE	DATE
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TERMS AND DEFINITION

TERMS	DEFINITION
Trials Registry	A verifiable record of the clinical trial be maintained to stop duplication and also to improve and preserve data integrity of clinical trials.
Clinical Trial	Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic/ pharmacokinetic effects of an investigational product(s), and/or to identify any adverse reaction(s) to an investigational product(s), with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.
Coordinating Investigator	An investigator assigned responsibility for the coordination of investigators at different centers participating in a multicenter trial.
Institutional Review Board (IRB)/ Institutional Ethical Committee (IEC)/Ethical Review Committee (ERC)	An independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocols and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.
Principal Investigator (PI)	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Sponsor-Investigator	An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.
Sub-investigator/ Co-Investigator (Co-PI)	Any individual member of the clinical trial team designated and supervised by the Principal investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows)

LIST OF ABBREVIATIONS

IRB: Institutional Review Board

IEC: Institutional Ethical Committee

ERC: Ethical Review Committee

PI: Principal Investigator

Co-PI: Co-Investigator

1. PURPOSE:

The purpose is to develop a registry for clinical trials with defined SOP describing the process to the researchers i.e. PI & Co-PI to register their clinical study, involving Human subjects, at DUHS.

2. SCOPE:

This SOP applies to all researchers employed at DUHS conducting/participating in any clinical study either academic, and/or sponsored, and/or Investigator initiated, being conducted under the domain of Dow University of Health Sciences and its Constituent institutions. The study has to be registered with pertinent information in DUHS clinical trial registry with synchronized policy.

3. RESPONSIBILITIES:

3.1 Institutional Heads/Principals/Directors are responsible for the implementation of the SOP.
3.2 Researchers must fill the registration form of DUHS trial registry via given link for their study being conducted in the premises of any institution/hospital/facility of DUHS
3.3 If the researchers do not register their study conducted in the DUHS registry, their study will not be owned by DUHS and the researchers will bear the consequences
3.4 Clinical Trials Unit (CTU), DUHS is responsible to register the clinical trial at clinicaltrials.gov, if requested by the researcher
3.5 DUHS CTU is responsible to track and maintain the registry

4. PROCEDURE:

4.1. All studies conducted in the premises of any institution/hospital/facility of DUHS must be registered in the DUHS trial registry through the provided link **[https://forms.gle/epV7j3tBGc8oFghH7].**

4.2. The registration number for the study will be issued by CTU-DUHS e.g. DUHS/CTU/YYYY/MM/0001 will be generated, i.e.

YYYY: 2019
MM: 01
0001: Serial No

4.3. For the registration, IRB approval is mandatory from DUHS before initiation of any trial (academic, sponsored or investigator initiated) in the premises of DUHS. The institutional IRB will also ensure the registration of trial at DUHS trial registry.

4.4. After IRB approval, the trial can be registered at clinicaltrials.gov. upon the request of the researchers via CTU with the information as follows: IRB approval letter, affiliation, official/ valid email ID & contact number of the researcher.

4.5. The study status must be submitted to CTU through email id [ctu@duhs.edu.pk]

regarding its cessation, termination or completion.

5. RELATED DOCUMENTS:

Nil

6. RELATED RECORDS:

DUHS Trial Registry Form

DUHS TRIAL REGISTRY FORM

- Principal investigator: _____
- Affiliation of Principal Investigator: _____
- Co-Investigator(s) /Sub Investigator(s): _____
- Affiliations of Co-Investigator(s)/Sub Investigator(s): _____
- Study Title:_____
- IRB Approval No.: _____

(IRB Approval Letter to be attached as pdf)

- Name of registry if registered in any other registry except DUHS: ☐_____ ☐ None
- Type of study:

☐Sponsored

☐Investigator initiated

☐Academic Research

☐Grant research

Information submitted by (name/affiliation/contact #):

_____

Note: This data is for record only in DUHS trial registry and there is no conflict of interest.