Government of Pakistan
Ministry of National Health Services
Regulation & Coordination

Drug Regulatory Authority of Pakistan

Serial. No. 0458

License No: CTS-0110.

Form – V

License to act as Clinical Trial Site

M/s Rawalpindi Medical University (RMU), Department of Infectious Diseases is hereby licensed to act as **Clinical Trial Site** for **Phase-III & IV Clinical Trials**, subject to GCP inspection before grant of registration/approval of Clinical trial/study at the premises situated at **Medical Unit, Holy Family Hospital Satellite Town RMU Rawalpindi.**

2. This license shall be subject to the following and in addition to the conditions as specified under Rule 04 of the Bio-Study Rules, 2017: -

(i) The license shall be valid for the period of three years from the date of issue unless earlier suspended or cancelled.
(ii) The licensee shall maintain the conditions of GCP and GLP.
(iii) Minimum safety standards shall be observed by the licensee.
(iv) License holder shall develop Protocols or SOPs for the conduct of studies or trials and get formal approval from the DRAP.
(v) License holder shall maintain adequate arrangement for storage of the study material as per protocol of the study.

3. Name of approved expert staff:

Prof. Dr. Muhammad Umar,
Vice Chancellor,
Rawalpindi Medical University,
Rawalpindi
CNIC No.37405-6364143-5

Date of issue: 27th **March, 2025.**
F.No.15-61/2020-CTS (55th CSC)

27.03.2025
Malik Muhammad Asad
Secretary (CSC)
(Seal)

Abdullah
Chairman (CSC)
(Seal)

Scope of the Clinical Trial Site licence.

The site is approved for Generalized Phase-III & IV Clinical Trials subject to GCP inspection before grant of registration / approval of Clinical trial/study.

Conditions for license.

(1) The applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an area free from offensive and obnoxious odours and other possible sources of contamination. The premises must have protective equipment for personnel and emergency firefighting arrangements.
(2) The applicant shall provide adequate space, facilities and equipment for the conduct of intended operations.
(3) The clinical trial, BA, BE, Bio-analysis activities shall be conducted under the active directions and personal supervision of competent technical staff consisting of at least one person holding a degree in the field of medical sciences from a recognized university in Pakistan or abroad and shall possess qualifications and experience which, in the opinion of the CSC, is appropriate and adequate for the purpose.
(4) Sufficient clinical support staff including phlebotomists duly qualified for the purpose must be available at the facility.
(5) The applicant shall ensure that, -

a. The staff involved in the clinical trial, BA, BE, Bio-analysis activities is fully trained in accordance with GCP and good laboratory practices (GLP) guidelines;
b. Audit procedures are pre-defined and relevant SOPs and guidelines are in place;
c. The licensed premises shall only be used for which it has been authorized by the licensing authority;
d. The licensed premises are maintained properly and shall, as far as possible, be orderly, clean and free from accumulated waste and vermin;
e. Unhygienic practices eating and smoking shall not take place in the area where research work is being conducted;
f. Sufficiently clean, appropriately ventilated toilet facilities, including facilities for washing and room for changing clothes, shall be available for the use of personnel where required;
g. Hygienic garments shall be worn by all staff in laboratory;
h. High standard of personnel hygiene shall be observed by all persons concerned with research work; and
i. No person known to be suffering from communicable disease or to be a carrier of such a disease and no person with open lesions or skin infection shall be engaged in research activities.

(6) The applicant shall provide-,

a. Adequate facilities for first aid and emergency medical treatment for the staff and trial subjects, including ambulance facility to transfer critical cases to the authorized tertiary care hospitals;
b. Medical inspection of workers at the time of employment and periodical checkup thereafter at least once a year;
c. Facilities for vaccination and inoculation against the enteric or any other epidemic group of diseases; and
d. Adequate precautions for safe-guarding the health of the workers, including measures to avoid accidents or diseases.

(7) Such other condition as required or advised by the CSC, keeping in view the nature of the case.