**Form – II**

**[See rule 7]**

**Application for approval and registration of clinical trial**

I/we ……………………………………………..………………………………………………..

NIC number ………………………………...of M/s …………………………………business address and telephone number and fax number……………hereby apply for approval or registration of clinical trial, titled……………….. ………………as per detail below:

(1) Name of Investigational product, including all available names; trade, generic or INN name etc. ..………………….……………………………………

(2) Purpose of trial defining the indication along with the anticipated cost of the project and sources of fund……………………………………………………………………..

(3) Phase of the clinical trial to be conducted and its proposed duration…………………

(4) Proposed center for trial………………………..……………………………………

(5) List of participating countries…………………………………………………………..

(6) Investigator brochure along with summary........…………..…………………………..

(7) Pre-clinical, clinical data, safety studies……………………………………………….

(8) Final protocol…………………………………………….…………………………….

(9) Detail of the investigator (Principal investigator and others along with CVs…..….

(10) IRB approval………..……………………………………………………………

(11) Ethical committee composition (names and designations)………..……………….

(12) Site approval by the Ethics committee………..……………………………….

(13) Informed consent (English and Urdu)………………….…………………………..

(14) Summary protocol or synopsis (Investigational Product)……………………………

(15) Adverse Event Reporting Form or CIOMS Form…………………….………………

(16) Name of the monitors or clinical research associate……………………………

(17) Evidence of registration in country of origin (GMP certificate along with CoPP or Free sale certificate) ………………………….……………………………………………

(18) Copy of registration letter if registered in Pakistan………………………………..

(19) Proposed label of investigational product…………………………………………

(20) Quantity of investigational products to be used in the trial along with justification

(Note: All the quantities of the investigational product should be procured from one single source)

UNDERTAKING

I/we hereby undertake / certify that the contents stated above are correct to the best of my/our knowledge and belief.

Name of the applicant

Signature

Date: ……. Seal of the firm/Company