**Form -III**

**[See rule 6]**

**Application for renewal of license to act as centre, clinical trial site, CRO or laboratory**

I/we …………………………………………………………………………………………….. NIC number ……………… ………………………………………... of M/s ……………………………..………………………………………………… …………... Business address and telephone number and fax number ……… ……… ……………………………………… …………………………...…………………………..…hereby apply for renewal of license for center or clinical trial site or CRO or laboratory.

2. Type of the studies meant for:-

(i) Bio-equivalence and Bio-availability studies

(ii) CRO

(iii) Laboratory

(iv) Clinical trials-

(a) Phase I

(b) Phase II

(c) Phase III

(d) Phase IV

3. I enclose:-

(a) Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their address, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors.

(b) Details of premises including lay out plan of the site.

(c) Details of the section wise equipment and machinery for required for the analytical or bio-analytical and clinical studies.

(d) Name and qualifications of the management, and

(e) Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.

**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