

**FORM CT-4A***(See rule 23)***INFORMATION TO INITIATE CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG  
AS PART OF DISCOVERY, RESEARCH AND MANUFACTURE IN INDIA**

I/We, .....(name and full postal  
address of the applicant) of ..... hereby inform to  
initiate the conduct clinical trial on new drug or investigational new drug.

The details of the application areas under:

1.Name of Applicant:	
2. Nature and constitution:  (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified)	
3. (i) Sponsor address, telephone number, mobile number, fax number and e-mail id:  (ii) Clinical trials site address, telephone number, mobile number, fax number and e-mail id:  (iii) Name and address of person responsible for payment of compensation, if any:  (iv) Address for correspondence: [corporate or registered office or clinical trial site]	
4. Details of new drugs or investigational new drugs and clinical investigation site [As per Annexure].	
5. Phase of the Clinical Trial	
6. Clinical trial protocol number with date:	
8. I hereby declared that I have already submitted the application under rule 21 of these rules and granted automatic approval under rule 23(2) and enclosed the documents as specified in the Second Schedule of the New Drugs and Clinical Trials rules, 2019.	
9. I hereby state and undertake that:  (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940, and the New Drugs and Clinical Trials Rules, 2019.	

Place:.....

Date:.....

Digital Signature

(Name and designation)

**Annexure:**

Details of new drugs or investigational new drugs:

Names of the new drug or investigational new drug:	
Therapeutic class:	
Dosage form:	

Composition:	
Indications:	

Details of clinical trial site:

Names and address of clinical trial site	
Ethics committee details:	
Name of investigator:	