

30-08-13

No. DCGI/MISC/2013(107)  
Directorate of General of Health Services  
Central Drugs Standard Control Organization  
FDA Bhawan, Kotla Road, New Delhi  
(O/o DCG (I))

OFFICE ORDER


**Subject:-** Furnishing of information in respect of financial support, fees, honorarium, payments in kind etc to be paid to the investigator as per contract entered into by the sponsor with the investigator / institution in clinical trials - regarding.

The Drugs and Cosmetics Rules provides that no clinical trial for a new drug, whether for clinical investigation or any clinical experiment by any institution, shall be conducted except under and in accordance with the permission in writing of the licensing authority defined in clause (b) of rule 21 i.e. Drugs Controller General (India). The detailed requirements and guidelines for undertaking clinical trials are provided under Schedule Y to the said rules. It is also specified under the rules that the clinical trial is conducted as per Good Clinical Practice (GCP) guidelines specified for the purpose.

The GCP guidelines provide that the sponsor should enter into a formal and legal agreement / contract with the investigator(s) / Institution(s) before the start of the trial on various terms of the trial. The agreement should also define the relationship between the investigator and the sponsor in matters such as financial support, fees, honorarium, payments in kind etc.

It has been decided that the information in respect of the payments made by the sponsor to the investigator for the conduct clinical trial should be made available.

In view of the above it is requested that the sponsor or his representatives while making an application to the office of DCG(I) for undertaking clinical trial shall also furnish the details of the contract entered by the sponsor with the investigator / institutions with regard to financial support, fees, honorarium, payments in kind etc to be paid to the investigator.

  
(Dr. G. N. Singh)  
Drugs Controller General (India)  
30.08.2013

To,  
Applicants for clinical trials