File No. 12-01/14-DC (Pt. 47)
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, New Delhi 110002

Dated 10.11.2015

CIRCULAR

Subject:- Requirement of permission for conduct of clinical trials for academic/research purposes that are non-regulatory in nature – regarding.

To deliberate stakeholders concerns and the way forward relating to some issues on conduct of clinical trials in India, two meetings were held on 20.08.2015 and 06.10.2015 under the Chairmanship of Secretary, Ministry of Health and Family Welfare in which experts including Secretary, D/o Health Research & Director General, ICMR and Director General Health Services were present.

As regards requirement of permission for conduct of clinical trials for academic/research purposes that are non-regulatory in nature, it was decided that the permission of DCG (I) shall not be required in such trials, provided that, the trials were approved by the respective Ethics Committee and they are not for regulatory submissions (i.e. if the trial are not for claiming permission of New Drug for marketing as per Drugs and Cosmetics Rules).

However, the Ethics Committee of the respective Institution may take a view in this regard. They should inform DCG (I) about the cases where permission of DCG (I) was not required. In case, no objection was received from DCGI within 30 days, the clearance of DCG (I) may be presumed.

This is communicated for information and necessary compliance by all concerned.

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

To:-

i) **All stakeholders through website of DCG (I).**
ii) **Zonal and Sub-zonal offices of CDSCO/ all officers of CDSCO (HQ).**

Copy to:-

i) **PS to Secretary, Ministry of Health and Family Welfare**
ii) **PPS to DGHS,**
iii) **PPS to JS(R).**