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, Kotala Road, New Delhi 110002

Date: 02-08-16

CIRCULAR

Subject: - Requirement of 50 bedded site for clinical trial-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 condition that no clinical trial shall be conducted at site having less than 50 bedded hospital, it has been decided to revise this condition & it is further decided that Ethics Committee shall examine & decide whether the clinical trial site is suitable for trial or not irrespective of number of bed.

However, it was also suggested that site shall have emergency rescue and care arrangements along with all other necessary facilities required for that particular clinical trial.

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) PS to AS,
IV) PS to JS(R).